

Talking with your Doctor



PFICVOICES®

Progressive Familial
Intrahepatic Cholestasis

Created in partnership with PFIC Network





About this Guide

This guide was created with input from families living with PFIC. It may help you prepare for your or a loved one's medical appointments and create a plan.

Many physicians do not have experience treating PFIC. Hepatologists (liver doctors) and gastroenterologists (doctors who specialize in digestive illness), may be your best sources of information. Learning about PFIC — and knowing which questions to ask — can help you advocate for yourself or your child.

Talking to Your Doctor About PFIC

Progressive familial intrahepatic cholestasis (PFIC) is a spectrum of rare, inherited liver diseases that can take a devastating toll on patients and their families. It can lead to severe itching (pruritus), slowed growth, and liver failure.

The itching can be so severe that children and infants may scratch through their skin.¹ Many patients turn to surgery, including liver transplant, to relieve the itching.^{2,3} Itching can also cause loss of sleep, poor attention, and lower school performance.¹

PFIC Signs and Symptoms

- Severe itching (pruritus)¹
- Yellowing of the skin (jaundice)¹
- Problems absorbing fats and fat-soluble vitamins (vitamins A, D, E and K)¹
- Problems with bile flow that can lead to liver failure⁴

Normally, the body makes bile acids that help with digestion, including absorbing fats and some vitamins. In people with PFIC, the normal flow of bile acids is disrupted. Bile acids build up in the body, damaging the liver.^{6,7}

PFIC affects 1 in 50,000 to 100,000 births.⁴ It is caused by mutations on different genes, including ATP8B1 (PFIC1), ABCB11 (PFIC2), ABCB4 (PFIC3), and others.⁵ PFIC1, PFIC2, and PFIC3 are the most common types.⁴ In addition, other rare forms of PFIC exist. They have some differences, but all cause problems with bile flow.⁵ Genetic testing can be relied on to support but not always definitively confirm the clinical diagnosis of PFIC.⁸

Easy Ways to Prepare for a Doctor Visit

Planning ahead for your doctor's visit can help you get the most out of each appointment. Here are steps you can take to prepare.



List your questions in advance.

During the course of a normal day, you may think of questions to ask your doctor. It can be easy to forget what you wanted to ask on the day of your actual appointment. Keeping an ongoing list of questions on your phone can help you remember important topics.



Bring a notebook, and maybe a companion.

Your healthcare provider may cover many topics. Taking notes can help ensure that you have a record of what you talked about. You can also ask the doctor or nurse to write down important points or print out a copy of the visit's notes. Also, it can be helpful to have someone with you to take notes and help you remember everything you wanted to talk about. If you have a young child, a companion can sit with your child while you're talking with the doctor.



Keep track of medications and dosages.

Tell your doctor about any medication or topical treatment being taken. Be sure to track dosages, how helpful the medications have been and side effects experienced.



Keep a journal and bring it to your appointment.

A written record can help you share symptoms and concerns. For instance, if you or your child often lose sleep because of severe itching, you may want to track sleeping patterns to discuss possible solutions with your doctor. You can also write down what you or your child eats to help your doctor address any nutritional needs.



Bring activities.

If you are taking a younger child to the doctor, a toy or game can help pass the time when you are waiting for the appointment to start.



Explain to your child what to expect.

Doctor's appointments can be a scary experience for young children. Help them prepare for the appointment by sharing what you know in a way that they may be able to understand.

During Your Appointment



Ask your most important questions first.

If you run out of time, you'll have the answers you need most.



Ask more questions.

If you don't understand something your doctor says, ask for a better explanation. Try to make sure that you leave the appointment feeling comfortable that all your questions have been answered. There is never a wrong question. Ask all questions that come to mind, even if you feel like you might know the answer.

Questions to Ask Your Provider

PFIC is a progressive condition, which means that it may get worse over time. Keeping a log of questions to ask at every appointment may be helpful for tracking disease changes or progression.

About PFIC Symptoms and Management

- What can I expect from PFIC? What risks and symptoms should I know about?
- What are the options for medication and how can they help? What side effects can I expect from the medications?
- Other than medication, what can I do to reduce symptoms?
- How will I know if and when my child needs a surgical procedure or transplant?
- Should my child get a genetic test for PFIC?
- Are there any resources that you can recommend that provide helpful information about PFIC and its symptoms?
- Is my child receiving adequate nutrition? What are signs or symptoms that we should be aware of to monitor vitamins?



About Your Appointments

- How often should I expect appointments? What does each appointment involve?
- What tests should I prepare for? How long will they take?
- When will I have my child's results?
- How can I keep track of my child's test results?
- If I have a concern about my child's symptoms, who should I contact?

Other Healthcare Needs

- Can you help me find a support group?
- Is all testing, including a genetic test, covered by insurance?
- How can living with PFIC affect my child's mental health? Do you have a psychologist you recommend if we need one?



Remember

Your doctor is a member of your healthcare team. Open communication will help build trust so you can achieve the best outcomes for your family.

This brochure is published by PFIC Voices (an initiative of Albireo Pharma) in partnership with the PFIC Network, a parent- and patient-led advocacy organization.

About Albireo

Albireo is committed to supporting people with PFIC, their families, and healthcare providers with resources to better understand and manage this devastating disease. The company is focused on the development of novel bile acid modulators to treat rare pediatric liver diseases, such as PFIC.

For more information and resources about Albireo's work with the PFIC Community, visit www.PFICvoices.com.

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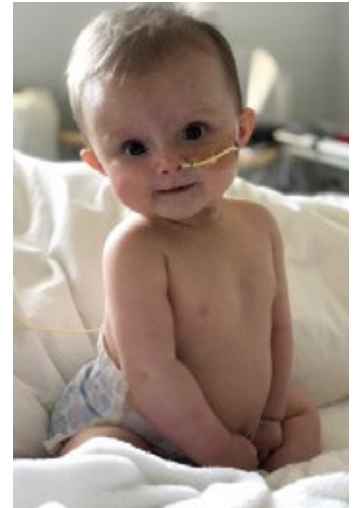
Progressive Familial Intrahepatic Cholestasis

WHAT IS PFIC?

Progressive familial intrahepatic cholestasis (PFIC) is a spectrum¹⁻⁴ of autosomal recessive genetic disorders in which cholestasis leads to liver failure.⁵

The estimated incidence of PFIC ranges from 1 in 50,000 to 100,000 births.⁵ Subtypes PFIC1, PFIC2 and PFIC3 are most common.⁵ In addition, other rare forms of PFIC exist with varying phenotypes, but all present with cholestasis.⁶

The most debilitating symptom of PFIC is pruritus (insatiable itching), which may be so severe that it leads to skin mutilation, loss of sleep, irritability, poor attention and impaired school performance.⁹ Up to 80% of PFIC patients had pruritus graded as severe (associated with abrasions, skin mutilation, hemorrhage or scarring).¹⁰



Survival analysis showed that at 18 years of age, only 44% of PFIC1 patients and 32% of PFIC2 patients were alive with their native liver.^{7,8}

Pruritus is a primary cause of surgical treatments and transplant, cited as the indication for surgical diversion in the majority of PFIC patients^{7,12} and for transplant in 50% of patients with PFIC1.¹³



SIGNS AND SYMPTOMS OF PFIC

The signs and symptoms of PFIC usually present in infancy in PFIC1 and PFIC2 and later in infancy to young adulthood in PFIC3.^{9,11} They may include:

• Pruritus

- Insatiable itching that may lead to skin mutilation, loss of sleep, irritability, poor attention and impaired school performance⁹

• Hepatic manifestations

- Jaundice (yellowing of the skin and whites of the eyes)⁹
- Elevated serum bile acids¹¹
- Hepatomegaly (enlarged liver)⁹
- Cirrhosis and end-stage liver disease¹¹
- Increased risk of liver cancer (PFIC2)⁹

• Gastrointestinal symptoms

- Gallstones¹¹
- Pancreatitis (PFIC1)¹¹
- Fat malabsorption⁹
- Diarrhea¹⁰
- Pale/discolored stools¹⁰

• Metabolic defects

- Fat-soluble vitamin (A, D, E and K) deficiency⁹
- Growth retardation⁹
- Bleeding (due to vitamin K deficiency)¹¹

DIAGNOSIS OF PFIC

Diagnosis should utilize a combined clinical, biochemical, radiological, and histological approach.⁵ In order to diagnose PFIC and the specific subtype, testing may include liver function tests, liver ultrasound and biopsy, immunohistochemistry, bile analysis, and genetic testing.⁹

SURGICAL TREATMENTS FOR PFIC

Surgical treatment options for PFIC include biliary diversion procedures and liver transplantation.⁹

PEBD decreases bile through ostomy.¹¹ Ostomy requires maintenance and induces fluid/electrolyte loss.^{11,14} In a study of 33 patients with cholestatic liver disease who had surgical biliary diversion, stoma complications occurred in 55% and 20 secondary surgeries were required.¹²

Patients undergoing liver transplant require long-term management with immunosuppressive medication, which can increase the risk of metabolic disorders such as diabetes, hypertension, hyperlipidemia, osteoporosis and chronic kidney disease.¹⁵ Nearly a quarter of liver transplants in children fail within the first 6 months, almost a third within 5 years and almost half within 20 years.¹⁶



RESOURCES FOR MORE INFORMATION

For information about treatments, talk to your doctor, and visit AlbireoAssist.com.

For more information on living with PFIC, visit:

PFIC Voices: PFICVoices.com

National Institutes of Health: <https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases>

PFIC Advocacy and Resource Network: <https://www.pfic.org/>

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PFIC VOICES[®]

Progressive Familial
Intrahepatic Cholestasis

A Guide for Patients and Families

What is PFIC?

Progressive familial intrahepatic cholestasis (PFIC) is a spectrum of rare, inherited liver diseases that can lead to severe itching (pruritus), lack of sleep, slowed growth, and liver failure.

The itching can be so severe that children and infants may scratch through their skin.¹ Many patients turn to surgery, including liver transplant, to relieve the itching.^{2,3}

PFIC affects 1 in 50,000 to 100,000 births.⁴ It is caused by mutations on different genes, including ATP8B1 (PFIC1), ABCB11 (PFIC2), ABCB4 (PFIC3), and others.⁵ PFIC1, PFIC2, and PFIC3 are the most common types.⁴ In addition, other rare forms of PFIC exist. They have some differences, but all cause problems with bile flow.⁵

PFIC1 and PFIC2 usually appear in the first months of life. PFIC3 may also occur later in infancy, in childhood, or even during young adulthood.⁴

What Happens in PFIC?

The body naturally makes bile acids that help with digestion, including absorbing fats and some vitamins. In people with PFIC, the normal flow of bile acids is disrupted. Bile acids build up in the body, damaging the liver.^{6,7}

What information is contained in this PFIC pamphlet, and who is it for?

PFIC stands for progressive familial intrahepatic cholestasis. It's a rare liver condition that requires medical attention and support. This pamphlet provides an overview of PFIC, how it is diagnosed and places you and your family can turn to for support. This overview is for the PFIC community and others who wish to learn basic information about this serious condition.



Signs and Symptoms

PFIC can cause signs and symptoms that may vary by person. Here are some of the most common.

Severe itching (pruritus).

Itching can be disruptive, leading to loss of sleep, poor attention, and lower school performance.¹

Jaundice. Yellowing of the skin and eyes may occur in the first months of life. In PFIC2 patients the jaundice may be permanent from the beginning, while in PFIC1 patients, jaundice may come and go at first, and become permanent later.⁴

Nutritional problems. PFIC patients may have problems absorbing fats and fat-soluble vitamins (vitamins A, D, E, and K). As a result, height and weight may be below normal.¹

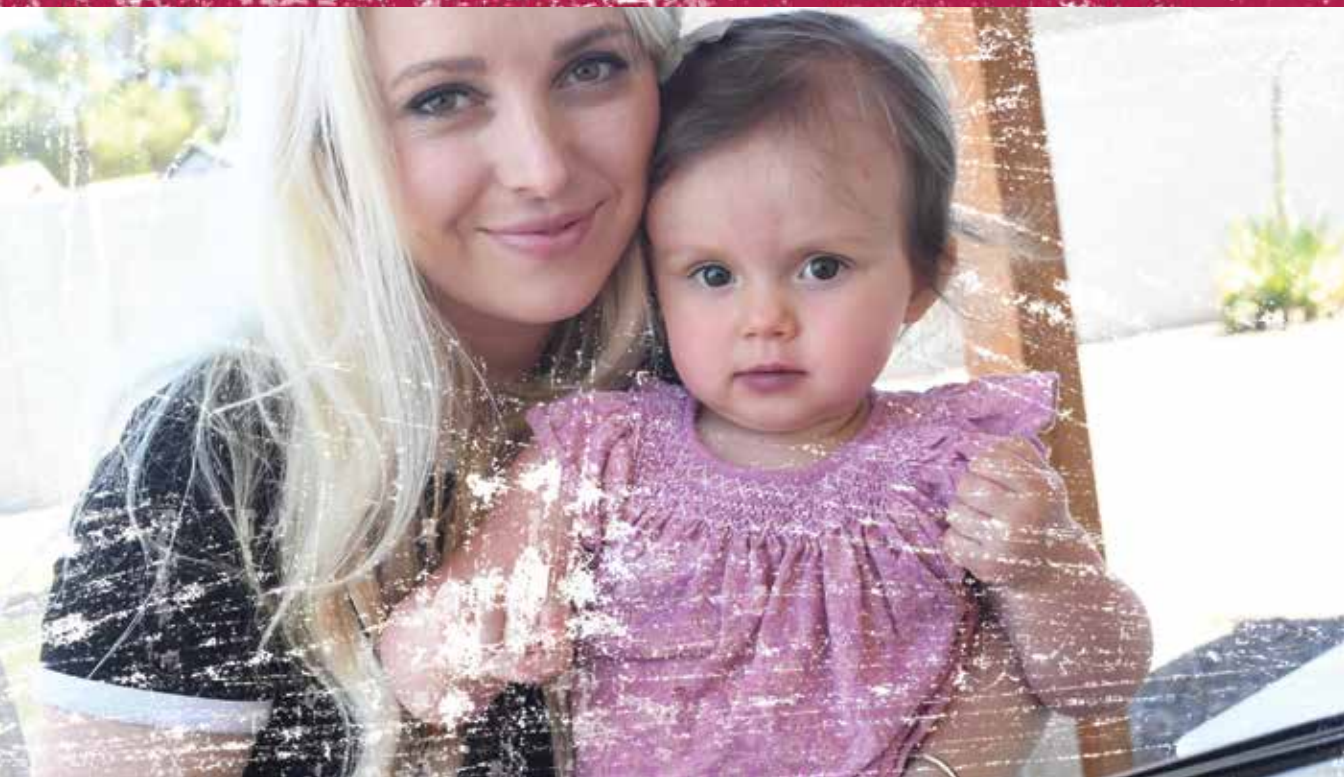
Liver problems. Problems with bile flow can damage the liver, potentially leading to liver failure.⁴

Other signs and symptoms. Other problems may include diarrhea and pale or discolored stools.⁸



"The itching associated with PFIC is life-changing for the child and the family. Children with PFIC are unable to sleep, and their development and ability to learn and grow suffer. Parents have to restrain their child to try to prevent them from scratching until they bleed. It's heartbreaking. It can become so debilitating that the itching brings us to recommend liver transplantation for the child. The itching can be that bad."

Dr. Jaime Chu
Pediatric Hepatologist
Mount Sinai Medical Center
New York
Consultant to Albireo



A Parent's Perspective

"When Sylvie was three weeks old, I noticed that when she was drinking her bottle, she would itch extensively on her face and her eyes. And I thought that was odd. The more she would get into her feeding, the itchier she'd get. I told my pediatrician and the doctors at the hospital. All of them said it was eczema or dry skin, so I used lotion for a long time. Nothing worked. It almost made it worse, because she would wipe the lotion into her eyes, and then she'd start screaming.

After we got the diagnosis of PFIC, the itching was the most debilitating thing for us. To get that managed was so important for everyday life and quality of life. And we just don't have that yet. We have these amazing days and horrible days. And I think, if we can manage that itching and getting her stable, that would be a miracle."

Season, mother of a daughter with PFIC

How is PFIC Diagnosed?

Your child's doctor may suspect PFIC if your child has itching or jaundice that does not go away. The doctor will try to rule out other, more common causes of jaundice first. A pediatrician may recommend sending a patient to a liver specialist for special tests, including blood tests, imaging, or liver biopsy. Physicians who specialize in the digestive system or gastrointestinal system are called gastroenterologists. Physicians who specialize in the liver are called hepatologists.

Genetic testing can be relied on to support but not always definitively confirm the clinical diagnosis of PFIC.⁹

PFIC is an autosomal recessive disorder.⁴ This means that a child must inherit an affected gene from both parents for the disease to be present. If the child only inherits the affected gene from one parent, he or she will be a "carrier" but will not have the disease.



Living with PFIC

Patients and their families should consult their healthcare providers for guidance on PFIC management. The following topics may be considered:

- **Skincare:** Patients with PFIC may have sensitive skin. It may be beneficial to cover skin as much as possible and to keep nails short.
- **Nutrition:** Talk with your doctor about possible ways to help manage nutritional deficiencies.

PFIC affects different people in different ways. Patients and parents should consult their healthcare providers for guidance on what may work best for them.

Surgical Interventions

When liver disease progresses, families may consider surgical options, including biliary diversion and liver transplantation.

Biliary Diversion. In surgical biliary diversion (or partial exterior biliary diversion, PEBD), bile is diverted out through the abdominal wall and, typically, collected in an ostomy bag outside the body. A less common approach called ileal exclusion (or internal biliary diversion), involves bypassing part of the small intestine and connecting it to the colon.

Liver Transplantation. Liver transplantation may be an option for some patients who experience progressing liver disease or severe itching.¹ Like all major surgeries, it has significant risks. Even when it is successful, it requires the patient to receive life-long immunosuppressive therapy to prevent the body from rejecting the new liver.¹⁰



Medical Intervention

A class of medications called IBAT inhibitors has been approved to treat severe itching in PFIC. While it is not known exactly how IBAT inhibitors work, it is thought that by reducing bile acids in the blood, they may reduce the amount of itching PFIC patients experience. Talk to your doctor about whether this approach is right for your child.

Hope for Patients and Families

PFIC Advocacy and Resource Network aims to improve the lives of patients and families worldwide affected by PFIC.

[PFIC.org](https://www.pfic.org)

Childhood Liver Disease Research Network (ChiLDReN) offers medical and patient advocacy support with clinical sites and research labs in the U.S.

[Childrennetwork.org](https://childrennetwork.org)

Children's Liver Disease Foundation (CLDF) is a UK-based charity dedicated to pediatric liver diseases. Download the CLDF PFIC brochure here:

<https://www.childliverdisease.org/wp-content/uploads/2018/01/PFIC.pdf>.

[Childliverdisease.org](https://www.childliverdisease.org)

ClinicalTrials.gov provides the public with information on clinical studies on a wide range of diseases and conditions, including PFIC.

[Clinicaltrials.gov](https://clinicaltrials.gov)

Global Genes is an advocacy organization committed to supporting the rare disease community.


[GlobalGenes.org](https://www.globalgenes.org)

American Liver Foundation (ALF) is a national, voluntary nonprofit organization dedicated to the prevention, treatment, and cure of hepatitis and other liver diseases through research, education, and advocacy.

[LiverFoundation.org](https://www.liverfoundation.org)

The National Organization for Rare Disorders (NORD), an independent nonprofit founded over 35 years ago, is leading the fight to improve the lives of patients with rare diseases. It does this by supporting patients and organizations, accelerating research, providing education, driving public policy and spreading awareness.

[Rarediseases.org](https://www.rarediseases.org)



"I would describe my daughter as a fighter. She has been through hell and back. It's amazing to see her perseverance. Despite it all, she is so happy, just a joy."

About Albireo

Albireo is committed to supporting people with PFIC, their families, and healthcare providers with resources to better understand and manage this devastating disease. The company is focused on the development of novel bile acid modulators to treat rare pediatric liver diseases, such as PFIC.

albireopharma.com

Special thanks to these organizations and the families living with PFIC for their support and contributions.

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Albireo Announces Publication of the PICTURE Study Highlighting the Caregiver Impact of PFIC, a Rare and Devastating Children's Liver Disease

February 14, 2022

- *PFIC caregivers reported high impact on mental and physical health, productivity, career prospects, sleep, relationships and finances*
- *Study suggests PFIC caregivers' quality of life may be comparable to that of cystic fibrosis caregivers*

BOSTON, Feb. 14, 2022 (GLOBE NEWSWIRE) -- Albireo Pharma, Inc. (Nasdaq: ALBO), a rare liver disease company developing novel bile acid modulators, today announced the publication of the PICTURE study in [Orphanet Journal of Rare Disease](#). A multinational, retrospective, cross-sectional study, PICTURE evaluated and quantified the impact that progressive familial intrahepatic cholestasis (PFIC) has on caregivers and found a significant caregiver-reported burden on health-related quality of life (HRQoL), impairment of daily activities, reduced sleep, impact on work productivity, career building challenges and relationship strain. The study illustrates for the first time that PFIC levies a substantial burden that extends beyond the individuals with the disease to those caring for them.

"PFIC is a devastating diagnosis. As a mother of a child with PFIC, I could not ask for a greater gift than being my daughter's advocate. With that said, the PICTURE study reinforces what many of us intuitively know – the challenges of caregiving are ever present and often overwhelming and exhausting," said Emily Ventura, Chief Executive Director of [PFIC Network](#), co-author of the PICTURE study and caregiver. "From loss of sleep to stress on finances and relationships, PICTURE reinforces that we must recognize the burden this disease puts on families and the importance of providing resources for PFIC caregivers, while continuing to fund research to improve treatment and care."

PFIC is a spectrum of rare, pediatric, genetic diseases of cholestasis, characterized by inadequate bile secretion, often requiring liver transplantation, and leading to liver failure and early death. The rare nature of PFIC has presented challenges to understanding and quantifying its impact on the daily lives of patients and their caregivers. The PICTURE study is the first and largest global study to evaluate and quantify the health-related quality of life responses from PFIC caregivers. The study showed that while caregivers report feeling fulfillment from their caregiving responsibilities, they also reported measurable negative impacts on many important health-related quality of life measures and work productivity. Specifically, the study found that:

- **PFIC substantially impacted caregivers' quality of life**
 - 82% of caregivers reported a strain on their relationships.
 - 86% of caregivers reported difficulty sleeping.
 - Notably, caregivers in the PICTURE study reported a median quality of life score of 67.7%. This score is lower in comparison with quality of life reported in a separate study of caregivers for individuals with cystic fibrosis, a similarly rare, genetic, progressive and lifespan-shortening condition (median 84.7 and 89.2 for mothers and fathers, respectively).
- **On average, PFIC caregivers reported high impairment in daily activities; more than half also experienced loss of work productivity**
 - 50% of caregivers reported an impact of their child's PFIC on their career-building efforts, with 73% of these citing the prevention of either their career progression or working more hours.
 - A third (36%) of caregivers reported missing an average of 13 workdays in the last three months, equating to 52 workdays lost in 12 months.
 - Of those who were working in paid employment, 36% stopped work due to caregiving needs, missing an average of 2.8 years of employment during their career.

"The PICTURE study provides, for the first time, a look at what it's really like for caregivers to live with the impact of this devastating, rare disease and the effect it has every day on families and adjacent communities," said Ron Cooper, President and CEO of Albireo. "At Albireo, we are committed to being the gold standard partner in the fight against PFIC and the findings from the PICTURE study reinforce the importance of providing access to Bylvay, the first approved drug treatment for patients with PFIC."

PFIC is a rare and devastating disorder affecting young children that causes progressive, life-threatening liver disease. Patients with PFIC have impaired bile flow, or cholestasis, and the resulting bile build-up in liver cells causes liver disease and symptoms such as intense itching, poor sleep and diminished quality of life. Albireo is committed to advancing research in PFIC and other rare cholestatic diseases. The Company recently received approval by the U.S. FDA for Bylvay, the first drug for the treatment of pruritus in all types of PFIC, and in Europe, Bylvay is approved for the treatment of PFIC. The Company is working with the community and patient advocacy groups like the [PFIC Network](#) and [Children's Liver Disease Foundation](#) to raise awareness of PFIC and support families managing the burden of this devastating disease.

About the PICTURE Study

The PICTURE study was a cross-sectional burden of illness study of physician and caregiver-reported information for 22 patients with PFIC type 1 or 2 in France, Germany, the United Kingdom and the United States from September 2020 through to March 2021. Physicians provided clinical and resource use data of PFIC patients at the time of consultation, via an electronic Case Report Form (eCRF). Caregivers of PFIC patients, recruited by the physician as they attended a clinical appointment with the patient, completed online specific self-completion questionnaires about the impact of the disease on their lives. The study was conducted under the guidance of an Expert Reference Group (ERG), consisting of a representative of academia as principal investigator, partnering charity and advocacy representatives as well as experts in the field of liver diseases. Funding for this study was provided by Albireo Pharma.

About Bylvay (odevixibat)

Bylvay is the first drug approved in the U.S. for the treatment of pruritus in patients 3 months of age and older in all types of progressive familial intrahepatic cholestasis (PFIC). The European Commission (EC) and UK Medicines and Healthcare Products Regulatory Agency (MHRA) have also granted marketing authorization of Bylvay for the treatment of PFIC in patients aged 6 months or older. Bylvay is available in Germany and the UK and will be available for sale in other European countries following pricing and reimbursement approval. A potent, once-daily, non-systemic ileal bile acid transport inhibitor, Bylvay acts locally in the small intestine. Bylvay can be taken as a capsule for patients that are able to swallow capsules, or opened and sprinkled onto food, which is a factor of key importance for adherence in a pediatric patient population. The most common adverse reactions for Bylvay are diarrhea, liver test abnormalities, vomiting, abdominal pain, and fat-soluble vitamin deficiency. The medicine can only be obtained with a prescription. For more information about using Bylvay, see the package leaflet or contact your doctor or pharmacist. For full prescribing information, visit <https://bylvay.com/>.

In the U.S. and Europe, Bylvay has orphan exclusivity for its approved PFIC indications, and orphan designations for the treatment of Alagille syndrome, biliary atresia and primary biliary cholangitis. Bylvay is being evaluated in the ongoing PEDFIC 2 open-label trial in patients with PFIC, in the BOLD Phase 3 study for patients with biliary atresia and the ASSERT Phase 3 study for Alagille syndrome.

About Albireo

Albireo Pharma is a rare disease company focused on the development of novel bile acid modulators to treat rare pediatric and adult liver diseases. Albireo's lead product, Bylvay, was approved by the U.S. FDA as the first drug for the treatment of pruritus in all types of progressive familial intrahepatic cholestasis (PFIC), and it is also being developed to treat other rare pediatric cholestatic liver diseases with Phase 3 trials in Alagille syndrome and biliary atresia, as well as an Open-label Extension (OLE) study for PFIC. In Europe, Bylvay has been approved for the treatment of PFIC with pricing listing in Germany and draft guidance from the National Institute for Health and Care Excellence (NICE), which recommends Bylvay for use in the National Health Service in the England, Wales and Northern Ireland UK. The Company has also completed a Phase 1 clinical trial for A3907 to advance development in adult cholestatic liver disease, with IND-enabling studies progressing with A2342 for viral and cholestatic liver disease. Albireo was spun out from AstraZeneca in 2008 and is headquartered in Boston, Massachusetts, with its key operating subsidiary in Gothenburg, Sweden. The Boston Business Journal named Albireo one of the 2019 and 2020 Best Places to Work in Massachusetts. For more information on Albireo, please visit www.albireopharma.com.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements, other than statements of historical fact, regarding, among other things: the plans for, or progress, scope, cost, initiation, duration, enrollment, results or timing for availability of results of, development of Bylvay, A3907, A2342 or any other Albireo product candidate or program; the pivotal trial for Bylvay in biliary atresia (BOLD); the pivotal trial for Bylvay in Alagille syndrome (ASSERT); the IND-enabling studies for A2342; the target indication(s) for development or approval; the timing for initiation or completion of or availability or reporting of results from any clinical trial, including the long-term open-label extension study for Bylvay in PFIC, the BOLD and ASSERT trials and the IND-enabling studies for A2342; or the potential benefits or competitive position of Bylvay or any other Albireo product candidate or program or the commercial opportunity in any target indication; Albireo often uses words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "planned," "continue," "guidance," or the negative of these terms or other similar expressions to identify forward-looking statements. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to: whether favorable findings from clinical trials of Bylvay to date, including findings in indications other than PFIC, will be predictive of results from other clinical trials of Bylvay; the timing for initiation or completion of, or for availability of data from, clinical trials of Bylvay, including BOLD and ASSERT, and the outcomes of such trials; Albireo's ability to obtain coverage, pricing or reimbursement for approved products in the United States or Europe; delays or other challenges in the recruitment of patients for, or the conduct of, the Company's clinical trials; and the Company's critical accounting policies. These and other risks and uncertainties that Albireo faces are described in greater detail under the heading "Risk Factors" in Albireo's most recent Annual Report on Form 10-K or in subsequent filings that it makes with the Securities and Exchange Commission. As a result of risks and uncertainties that Albireo faces, the results or events indicated by any forward-looking statement may not occur. Albireo cautions you not to place undue reliance on any forward-looking statement. In addition, any forward-looking statement in this press release represents Albireo's views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. Albireo disclaims any obligation to update any forward-looking statement except as required by applicable law.

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