

Category

Best Pharmaceutical Product

General Information**Company Name ***

AbbVie

Product/Solution Name *

ELAHERE®

Compound/Tech Name*

mirvetuximab soravtansine-gynx

Trade Name *

ELAHERE®

Corporate Name *

AbbVie

Date of Approval *

2022-11-14

Indications *

ELAHERE® (mirvetuximab soravtansine-gynx) is a folate receptor alpha (FRa)-directed antibody and microtubule inhibitor conjugate for the treatment of adult patients with FRa positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who received 1-3 prior treatments and screened with an FDA-approved biomarker test.

words remaining :

456

Therapeutic Areas *

Gynecological oncology

words remaining :

498

*Kindly clearly label your files with company name and asset name.

Background information and need for drug / device

(please be as specific as possible in your description; limit 500 words)

ELAHERE® is the first and only fully FDA approved FRa-targeted antibody-drug conjugate (ADC) approved in the world for ovarian cancer, and the first new medication approved specifically for platinum-resistant ovarian cancer (PROC) since 2014.

Ovarian cancer is the leading cause of gynecologic cancer mortality worldwide and responsible for over 150,000 deaths yearly. Standard-of-care treatment for newly diagnosed women includes surgery and platinum- and taxane-based combination chemotherapy; however, 80% of patients relapse during or after treatment and eventually develop resistance to chemotherapy. For many patients, cancer often comes back within 6 months of completing chemotherapy. Prior to ELAHERE's approval, patients with PROC faced a bleak future due to low response rates to chemotherapy, chemotherapy-related toxicities and the lack of other treatment options - resulting in a median low survival of less than 12 months. These patients with PROC desperately needed a better therapeutic option that is not based on chemotherapy. The approval of ELAHERE, a non-chemotherapy treatment, offered new hope to these patients.

words remaining :

338

*Kindly clearly label your files with company name and asset name.

History of the development of the solution/product *

(please be as specific as possible in your description; 500 words)

ELAHERE is designed to target and kill tumor cells while sparing healthy tissue, offering a significantly improved safety profile and response against PROC. Having entered development more than a decade ago, ELAHERE incorporates multiple ADC innovations including: a novel monoclonal antibody that selectively binds to FRa, a next-generation tubulin-targeting DM4 maytansinoid payload designed for efficient cancer-cell killing, and improvements in linker/payload conjugation with a cleavable sulfo-SPDB linker. Now with ELAHERE, patients have a targeted therapy with a well-characterized safety profile and proven efficacy in FRa-positive, PROC. Before ELAHERE's approval, there were no specific biomarker-driven therapies successfully developed for platinum-resistant disease. One of the first patients to receive ELAHERE said: "I really didn't have much choice before this drug became an option. I've had 4 cycles of ELAHERE and I can't tell you how much this has changed my life...It's given me life again!"

words remaining :

357

*Kindly clearly label your files with company name and asset name.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition *

Ovarian cancer is the leading cause of gynecologic cancer mortality worldwide and responsible for over 150,000 deaths yearly. Standard-of-care treatment for newly diagnosed women includes surgery and platinum- and taxane-based combination chemotherapy; however, 80% of patients relapse during or after treatment and eventually develop resistance to chemotherapy. For many patients, cancer often comes back within 6 months of completing chemotherapy. Prior to ELAHERE's approval, patients with PROC faced a bleak future due to low response rates to chemotherapy, chemotherapy-

related toxicities and the lack of other treatment options - resulting in a median low survival of less than 12 months. These patients with PROC desperately needed a better therapeutic option that is not based on chemotherapy. The approval of ELAHERE, a non-chemotherapy treatment, offered new hope to these patients. ELAHERE is designed to target and kill tumor cells while sparing healthy tissue, offering a significantly improved safety profile and response against PROC.

words remaining :

349

*Kindly clearly label your files with company name and asset name.

Please provide appropriate references (PubMed, Abstract, Website) *

ELAHERE® (mirvetuximab soravtansine-gynx) HCP Website (elaherehcp.com)

ELAHERE® (mirvetuximab soravtansine-gynx) for Injection, a Prescription medicine, Patient Website
AbbVie.com

*Kindly clearly label your files with company name and asset name.