Oasmia's Partner Elevar Provides an Update on Apealea Development Plans in Ovarian Cancer

~ Elevar and Oasmia to Host Audiocast and Telephone Conference Today at 16:00 CET ~

Uppsala, Sweden, December 3, 2020 – Oasmia Pharmaceutical AB, an innovation-focused specialty pharmaceutical company, today shared an update from its partner, Elevar Therapeutics, on the development plan for Apealea (paclitaxel micellar), a non-Cremophor based formulation of paclitaxel, in ovarian cancer. Since acquiring rights to Apealea at the end of March 2020, Elevar has had interactions with the FDA and received guidance for further advancing the development program for Apealea. Following these interactions, Elevar has decided to complete two new studies with Apealea, which will both be initiated in the first half of 2021 before filing a new drug application (NDA) with the U.S. Food and Drug Administration (FDA).

- The first study planned by Elevar is a pharmacokinetics study, which Elevar aims to initiate in the first half of 2021. The study is expected to take approximately 12 months to complete.
- Elevar is also planning to initiate a pivotal superiority study to investigate the safety and efficacy of Apealea in epithelial ovarian cancer. Elevar is working closely with The GOG Foundation (GOG-F) through its GOG Partners program in the U.S. to plan and execute this global study in the first half of 2021. This study is expected to take approximately 24-36 months to complete.

"Despite the global pandemic, Elevar has made great strides advancing the ovarian cancer development program for Apealea. We have designed a clinical program for Apealea with advice from the FDA as well as advisory boards consisting of global thought leaders," said Alex Kim, Chief Executive Officer of Elevar Therapeutics. "Paclitaxel is a well-known chemotherapy agent that has been proven effective to treat ovarian cancer, yet in the U.S. the approved formulations use Cremophor-EL, which may induce serious side effects, require longer infusion times, and may not be suitable for patients who have certain co-morbidities or cannot tolerate steroids pre-treatment. Elevar is dedicated to making Apealea available to patients with epithelial ovarian cancer worldwide, and we expect that it will be the first non-cremophor formulation approved in this indication by the U.S. FDA."

"The clinical benefit of paclitaxel has been well-established in oncology," said David M. O'Malley, M. D., Professor and Director, Division of Gynecologic Oncology, Co-Director, Gyn Oncology Phase I Program, The Ohio State University and the James Cancer Center. "Having a non-Cremophor formulation of paclitaxel micellar has the potential to contribute to improved clinical outcomes and treatment experiences for epithelial ovarian cancer patients."

In addition, Elevar is exploring the potential utility of Apealea in other indications beyond ovarian cancer.

Apealea received market authorization from the European Commission in 2018, which was the first approval in Europe for a non-Cremophor EL paclitaxel in epithelial ovarian cancer. Apealea has received Orphan Drug Designation from the FDA for the treatment of epithelial ovarian cancer, which could lead to potential benefits including seven years of market exclusivity.

"These two new studies of Apealea may potentially help to secure a successful registration in the U. S. and provide new data to support a strong product label – critical for commercial success. Through our partnership with Elevar, Oasmia will, as previously stated, receive double digit royalties on all sales and milestones associated with any indication successfully approved," commented François Martelet, M.D., Chief Executive Officer of Oasmia.

Since March, Elevar has also made significant progress to enable patients to access Apealea outside of the U.S.:

- Elevar and Tanner Pharma launched a global named patient program to provide access to Apealea in areas outside of the U.S. where Apealea is not commercially available.
- Elevar signed an agreement with Taiba Middle East FZ LLC for the commercialization of Apealea in the Middle East and North Africa Region.

Elevar is in active discussion with a number of other potential commercial partners for Apealea in regions around the world, including Europe.

Conference Call Details
Elevar and Oasmia will host an audiocast and telephone conference on December 3, 2020, at 16: 00 CET, with the following participants:

- Francois Martelet, CEO of Oasmia Pharmaceutical AB
- Alex Kim, CEO of Elevar Therapeutics Inc.
- Mark Gelder, MD, Head of Medical Affairs at Elevar Therapeutics Inc.

Weblink: https://tv.streamfabriken.com/press-conference-december

Participant Dial-In Numbers:

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About Apealea (paclitaxel micellar)
Apealea is a patented, water-soluble, intravenously injectable, non-Cremophor based formulation of paclitaxel. Paclitaxel is a well-known chemotherapy agent used to treat breast, ovarian, lung, bladder, prostate, melanoma, and esophageal cancer, as well as other types of solid tumor cancers. Cremophor EL, is a formulation vehicle used for various poorly-water soluble drugs, including the anticancer agent paclitaxel and is associated with allergic reactions. Apealea received market authorization by the European Commission in November 2018, making it Europe's first non-Cremophor EL formulation of paclitaxel approved for use in ovarian cancer.

About Ovarian Cancer
Ovarian cancer is one of the most common female cancers affecting the primary reproductive organs. It is the fifth most common cancer among women in the U.S., with a prevalence rate of nearly 230,000 women, and accounts for more deaths than any other cancer of the female reproductive system., About half of the women who are diagnosed with ovarian cancer are 63 years or older and many of these patients are predisposed to age-related comorbidities, such as diabetes, which can influence treatment response and prognosis.iii,

About Oasmia Pharmaceutical AB
Oasmia is a specialty pharma company dedicated to improving the lives of patients by enhancing the intravenous delivery of established and novel drugs in significant diseases, including cancer. Product development is based on the Company's proprietary drug delivery technology platform XR-17™ which can be applied to medicines used in many therapeutic areas, to develop water soluble formulations of drugs that currently require chemical solubilizers for dissolution. The first product approved using this technology is Apealea (paclitaxel micellar). Apealea has received market authorization in the European Union and several other territories for the treatment of first relapse in platinum-sensitive ovarian cancer, in combination with carboplatin. The Company is making Apealea accessible to patients through its partnership with Elevar Therapeutics, together with its existing commercial operations in the Nordic region. Oasmia's shares are traded on the Nasdaq Stockholm stock exchange (ticker: OASM). To find out more about Oasmia please visit www.oasmia.com.

About Elevar Therapeutics
Elevar Therapeutics (formerly LSK BioPharma) is a rapidly growing, fully integrated biopharmaceutical company built on the promise of elevating treatment experiences and outcomes for patients who have limited or inadequate therapeutic options. Elevar's lead proprietary drug candidates include rivoceranib (apatinib) and Apealea (paclitaxel micellar). Rivoceranib is the first small-molecule tyrosine kinase inhibitor (TKI) to be approved in gastric cancer (China, Dec 2014). It has been granted Orphan Drug designation in the U.S., Europe and South Korea and has been clinically tested in over 1,000 patients worldwide in numerous cancer indications. Apealea (paclitaxel micellar) is a non-Cremophor EL based formulation of paclitaxel that received market authorization by the European Commission in November 2018, making it Europe's first non-Cremophor EL formulation of paclitaxel approved for use in ovarian cancer. Elevar Therapeutics has offices in Utah, California and South Korea, and additional information is available at www.elevartherapeutics.com.

About The GOG Foundation, Inc. (www.gog.org)
The GOG Foundation, Inc. (GOG Foundation) is a not-for-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials development, execution, analysis and distribution of results. The GOG Foundation is the only group in the United States that focuses its research on women with pelvic malignancies, such as cancer of the ovary, uterus, and cervix. The GOG Foundation is multi-disciplinary in its approach to clinical trials, and includes gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, nurses, statisticians, basic scientists, quality of life experts, data managers, and administrative personnel.

About GOG Partners
Supported by industry, GOG Partners has been structured to work directly with pharmaceutical organizations and operate clinical trials outside the National Cancer Institute (NCI) framework. By providing an alternative venue for patient accrual and site infrastructure support, GOG Partners has helped stabilize the national gynecologic clinical trials network.

For More Information:

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[1] SEER Cancer Stat Facts: Ovarian Cancer. National Cancer Institute. http://seer.cancer.gov/statfacts/html/ovary.html. Accessed November 24, 2020.
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[1] Minlikeeva, Albina N., et al. "History of hypertension, heart disease, and diabetes and ovarian cancer patient survival: evidence from the ovarian cancer association consortium." Cancer Causes & Control 28.5 (2017): 469-486.

This information is information that Oasmia Pharmaceutical is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2020-12-03 13:02 CET.

Attachments

Oasmia’s Partner Elevar Provides an Update on Apealea Development Plans in Ovarian Cancer