ObsEva Announces Positive Topline Results for Linzagolix 200 mg with Add-Back Therapy in the Phase 3 EDELWEISS 3 Trial in Patients with Moderate-to-Severe Endometriosis-Associated Pain

-Once daily linzagolix 200 mg with ABT met both co-primary efficacy objectives, demonstrating reductions in dysmenorrhea and non-menstrual pelvic pain versus placebo at 3 months; showed statistically significant and clinically meaningful improvements versus placebo in ranked secondary endpoints of dysmenorrhea, non-menstrual pelvic pain, dyschezia, overall pelvic pain, and ability to perform daily activities at 6 months-

-Once daily linzagolix 75 mg without ABT demonstrated statistically significant improvement for dysmenorrhea versus placebo and showed improvement but did not meet the co-primary objective of reduction in non-menstrual pelvic pain at 3 months; also showed improvement in secondary endpoints at 6 months-

-Both doses of linzagolix were well-tolerated with minimal bone mineral density (BMD) decrease and few adverse events occurring in over 5% of patients in either active treatment arm -

-Results support continued development of linzagolix with ABT and non-ABT doses for the treatment of endometriosis-

-Additional data from the post-treatment follow-up of EDELWEISS 3 are expected in 2Q 2022 and from the post-treatment follow-up of the extension study in 4Q 2022-

-Conference call and webcast with Dr. Hugh Taylor to be held today at 8:00 a.m. EST-

Ad hoc announcement pursuant to Art. 53 LR of the SIX Swiss Exchange

GENEVA, Switzerland January 6, 2022 – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies for women’s health, today announced positive topline results from the Phase 3 EDELWEISS 3 trial of linzagolix, an oral GnRH antagonist, in women with moderate-to-severe endometriosis-associated pain (EAP). Two doses were tested, a 200 mg once-daily dose of linzagolix in combination with add-back therapy (ABT) and a 75 mg dose of linzagolix without ABT.

The 200 mg dose met the co-primary efficacy objectives, demonstrating reductions in dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP) at 3 months. There were statistically significant and clinically meaningful improvements in the first five ranked secondary endpoints at 6 months: dysmenorrhea, non-menstrual pelvic pain, dyschezia, overall pelvic pain, and ability to do daily activities. The 75 mg dose without ABT demonstrated a statistically significant reduction versus placebo in DYS at 3 months. Although it showed improvement in NMPP at 3 months, it did not reach statistical significance versus placebo, and thus did not meet the co-primary efficacy objective. Improvements were also observed at 6 months in the first five ranked secondary endpoints, as for the 200 mg plus ABT dose. Both linzagolix doses were generally well-tolerated with minimal BMD decrease and few adverse events occurring in more than 5% of patients up to 6 months.

“While there have been recent advances in non-surgical endometriosis treatment, there is still a critical need for therapeutic options for women who suffer from this chronic condition,” said Hugh Taylor, MD, Professor and Chair of Obstetrics and Gynecology at Yale University. “Once daily linzagolix 200 mg with
ABT demonstrated excellent efficacy along with minimal changes in bone mineral density, suggesting this dose may be used for long-term treatment. Availability of medical therapies that can be used long-term is important for this typically younger patient population. The demonstration of improvement in dyschezia is of particular interest as this is the first Phase 3 trial of an oral GnRH antagonist to report efficacy in this common and debilitating symptom of endometriosis.”

Elizabeth Garner, MD, MPH, Chief Medical Officer of ObsEva, commented, “We are extremely pleased by the results highlighting the promising clinical profile of linzagolix 200 mg once-daily dose with ABT for women with moderate-to-severe EAP and the potential to be a leading GnRH option that balances safety and efficacy. Furthermore, by effectively addressing debilitating pain symptoms, linzagolix may improve overall quality of life and the ability to perform daily activities. While the 75 mg dose did not meet the NMPP endpoint, the statistically significant and clinically meaningful responder rates versus placebo for dysmenorrhea at 3 months and the evidence of clinical activity and tolerability at 6 months are encouraging. We plan to complete the Phase 3 program for this important indication and intend to further explore a non-ABT dose option as we remain dedicated to meeting the individual treatment needs and preferences of all women.”

**Top-line Efficacy Analysis**

**Co-Primary Endpoints at 3 Months**
The co-primary efficacy endpoints of DYS and NMPP were based on subject-reported symptoms recorded daily via an electronic diary using a verbal rating scale (VRS) of 0 (no pain) through 3 (severe pain). The responder thresholds for monthly pain scores were defined as a reduction of at least 1.1 for DYS and 0.8 for NMPP. P <0.05 denotes a significant difference from placebo. The responder rates for DYS were 73% for linzagolix 200 mg with ABT (p<0.001), 44% for linzagolix 75 mg (p<0.001), and 24% for placebo. The responder rates for NMPP were 47% for linzagolix 200 mg with ABT (p=0.007), 39% for linzagolix 75 mg (p=0.279), and 31% for placebo.

**Secondary Endpoints at 6 Months**
For linzagolix 200 mg with ABT, the first five ranked secondary endpoints achieved statistical significance compared to placebo. These were improvements at 6 months in dysmenorrhea, non-menstrual pelvic pain, dyschezia, overall pelvic pain (OPP), and difficulty in doing daily activities. The 75 mg also showed improvements in these endpoints. The complete results for the ranked secondary endpoints are shown in the table below. P<0.05 denotes a significant difference from placebo for each endpoint when p<0.05 for all higher ranked endpoints (including both co-primary endpoints).
## Endpoint at 6 Months

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Placebo</th>
<th>LGX 75 mg</th>
<th>p-value</th>
<th>LGX 200 mg + ABT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in DYS score</td>
<td>-0.66</td>
<td>-1.1</td>
<td>&lt;0.001</td>
<td>-1.83</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Change in NMPP score</td>
<td>-0.66</td>
<td>-0.84</td>
<td>0.048</td>
<td>-0.92</td>
<td>0.002</td>
</tr>
<tr>
<td>Change in dyschezia score</td>
<td>-1.41</td>
<td>-1.98</td>
<td>0.015</td>
<td>-1.99</td>
<td>0.012</td>
</tr>
<tr>
<td>Change in OPP</td>
<td>-2.19</td>
<td>-2.84</td>
<td>0.024</td>
<td>-3.39</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Change in difficulty of doing daily activities</td>
<td>-19.47</td>
<td>-27.37</td>
<td>0.001</td>
<td>-35.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Change in dyspareunia score</td>
<td>-0.82</td>
<td>-1.04</td>
<td>0.100</td>
<td>-1.01</td>
<td>0.184</td>
</tr>
<tr>
<td>No analgesic use</td>
<td>13.2%</td>
<td>30.9%</td>
<td>&lt;0.001</td>
<td>44.50%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No opiate analgesic use</td>
<td>97.0%</td>
<td>93.8%</td>
<td>0.420</td>
<td>97.00%</td>
<td>1.000</td>
</tr>
</tbody>
</table>

### Safety Results at 6 Months

Linzagolix was generally well-tolerated with minimal bone mineral density decrease; mean BMD decrease at the lumbar spine was 0.79% for linzagolix 200 mg with ABT and 0.89% for linzagolix 75 mg. Few adverse events were observed in over 5% of patients in any active treatment arm; these included headache (10.5%, 8.1%, and 8.0%), hot flush (6.8%, 7.5%, and 2.5%), and fatigue (6.8%, 3.8%, and 2.5%) for the 200 mg with ABT, 75 mg, and placebo groups, respectively.

"These positive data continue to build on the compelling foundation that underscores the potential clinical utility of linzagolix as an effective once daily oral treatment for the millions of women worldwide suffering chronically from endometriosis or uterine fibroids," said Brian O’Callaghan, CEO of ObsEva. “We remain dedicated to providing flexible treatment options for women and look forward to further development of linzagolix in the endometriosis indication. As we continue to build and drive our linzagolix clinical development program forward, I would like to sincerely thank our investigators, employees, partners and most importantly the women who participated in our trials."

### Conference Call and Webcast Today

ObsEva will host a conference call and audio webcast with Dr. Hugh Taylor today, January 6 at 8:00 a.m. Eastern Time/2:00 p.m. Central European Time to discuss Phase 3 EDELWEISS 3 trial results of linzagolix. Investors may participate by dialing 1-877-407-9208 for U.S. callers or +1-201-493-6784 for international callers and refer to conference ID 13725902. A live or archived webcast of the conference call can be accessed here or under the “Investors” section of ObsEva’s website www.ObsEva.com.

### About the Phase 3 EDELWEISS Program in Endometriosis

EDELWEISS 3 (Europe and the U.S.) was a randomized, double-blind, placebo-controlled, Phase 3 trial that analyzed 484 women with moderate-to-severe EAP. The study was designed to evaluate the long-term efficacy and safety of linzagolix, with a co-primary endpoint of reduction in both dysmenorrhea and non-menstrual pelvic pain at 3 months, along with stable or decreased use of analgesics for EAP. The study included a 200 mg once-daily dose in combination with ABT (1 mg estradiol / 0.5 mg norethindrone acetate), and a 75 mg once-daily dose without ABT. Subjects who completed the initial 6-month treatment period were offered to enter a 6-month treatment extension under the Edelweiss 6 protocol or to enter a 6-month post-treatment follow-up period. Results from the post-treatment follow-up of EDELWEISS 3 are expected in 2Q 2022 and from the post-treatment follow-up of the extension study in 4Q 2022. Additional information about this study can be found here.
About Endometriosis
The World Endometriosis Research Foundation estimates that endometriosis affects one in ten women during their reproductive years, representing approximately 176 million women worldwide between the ages of 15 and 49.

Endometriosis is a disease in which the endometrium (tissue lining the inside of the uterus) is found outside the uterus, where it induces a chronic inflammatory reaction that may result in scar tissue. It is primarily found on the pelvic peritoneum, on the ovaries, in the rectovaginal septum, on the bladder and bowel. The most common symptom of endometriosis is pelvic pain, which often correlates to the menstrual cycle. Patients may also experience painful ovulation, pain during or after sexual intercourse (dyspareunia), dyschezia (difficult or painful defecation), heavy bleeding, fatigue, and infertility. Endometriosis pain can be so severe and debilitating that it affects day-to-day activities and has a negative impact on general, physical, mental, and social well-being. Endometriosis treatments aim first to alleviate pain, then to remove or decrease the size and number of endometrial lesions, and possibly improve fertility.

About Linzagolix
Linzagolix is a novel, once daily, oral GnRH receptor antagonist with a potentially best-in-class profile. Linzagolix has completed clinical trial development for the treatment of heavy menstrual bleeding associated with uterine fibroids and is currently in late-stage clinical development for the treatment of pain associated with endometriosis. ObsEva licensed linzagolix from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for the product. Linzagolix is not currently approved anywhere in the world.

About ObsEva
ObsEva is a biopharmaceutical company developing and commercializing novel therapies to improve women’s reproductive health and pregnancy. Through strategic in-licensing and disciplined drug development, ObsEva has established a late-stage clinical pipeline with development programs focused on new therapies for the treatment of uterine fibroids, endometriosis, and preterm labor. ObsEva is listed on the Nasdaq Global Select Market and is traded under the ticker symbol “OBSV” and on the SIX Swiss Exchange where it is traded under the ticker symbol “OBSN”. For more information, please visit www.ObsEva.com

About Kissei Pharmaceutical Co., Ltd.
Kissei is a Japanese pharmaceutical company based on the management philosophy “contributing to society through high-quality, innovative pharmaceutical products” and “serving society through our employees.” As a strong R&D-oriented corporation, it concentrates on providing innovative pharmaceuticals to patients worldwide in the focus fields of urology, nephrology/dialysis, gynecology and rare/intractable diseases.

Cautionary Note Regarding Forward-Looking Statements
Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe”, “expect”, “may”, “plan”, “potential”, “will”, and similar expressions, and are based on ObsEva’s current beliefs and expectations. These forward-looking statements include expectations regarding the clinical development of ObsEva’s product candidates, including the timing, advancement and potential therapeutic benefits of linzagolix, the potential for linzagolix to be a commercially competitive product, expectations regarding regulatory and
development milestones, including the potential timing of regulatory submissions to the EMA and FDA and ObsEva’s ability to obtain and maintain regulatory approvals for its product candidates, and the results of interactions with regulatory authorities. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials and clinical development, including the risk that the results of earlier clinical trials may not be predictive of the results of later stage clinical trials, related interactions with regulators, ObsEva’s reliance on third parties over which it may not always have full control, and the capabilities of such third parties, the impact of the ongoing novel coronavirus outbreak, and other risks and uncertainties that are described in the Risk Factors section of ObsEva’s Annual Report on Form 20-F for the year ended December 31, 2020 filed with Securities and Exchange Commission (SEC) on March 5, 2021 and in the Report on Form 6-K filed with the SEC on November 4, 2021, and other filings ObsEva makes with the SEC. These documents are available on the Investors page of ObsEva’s website at www.ObsEva.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to ObsEva as of the date of this release, and ObsEva assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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