Press Release

Astellas Highlights VEOZAH™ (fezolinetant) Data at the 2023 Annual Meeting of The Menopause Society

Pooled analyses from pivotal Phase 3 SKYLIGHT™ studies provide new insights into fezolinetant for the treatment of moderate to severe VMS due to menopause

Additional presentations highlight real-world data on the prevalence and impact of VMS

TOKYO, September 19, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") will share new pooled efficacy and safety analyses from the pivotal Phase 3 SKYLIGHT™ studies for VEOZAH™ (fezolinetant), its first-in-class treatment for moderate to severe vasomotor symptoms (VMS) due to menopause, during the 2023 Annual Meeting of The Menopause Society from September 27-30. Real-world data on the prevalence and impact of VMS will also be presented. VMS, characterized by hot flashes and/or night sweats, are common symptoms of menopause.[1,2]

Marci English, Vice President, Head of BioPharma Development, Astellas
"At this year's meeting, we are excited to share new subgroup analyses from our pivotal Phase 3 SKYLIGHT studies. These analyses provide valuable insights into the efficacy and safety of VEOZAH in women who are unable or unwilling to take hormone therapy, as well as the efficacy of VEOZAH on VMS experienced at night. The totality of the research being presented adds to our collective knowledge of how VMS impacts individuals and is representative of our commitment to addressing unmet medical needs."

Highlights at the 2023 Annual Meeting of The Menopause Society include:

- Two separate pooled analyses from SKYLIGHT 1 and SKYLIGHT 2 examining the efficacy and safety of fezolinetant in patients unsuitable for or unwilling to take hormone therapy, as well as the efficacy of fezolinetant on night-time VMS episodes
- Pooled data from SKYLIGHT 1, SKYLIGHT 2 and SKYLIGHT 4 assessing the safety and tolerability of fezolinetant over 52 weeks
- A real-world study assessing treatment satisfaction among women with moderate to severe VMS, as well as physicians who treat women with VMS in the U.S.
- Additional presentations highlighting the diverse experiences of women with VMS in the U.S., VMS diagnosis disparities in the U.S. based on sociodemographic characteristics, and the prevalence and impact of VMS among women in Canada

Following are Astellas' presentations at the 2023 Annual Meeting of The Menopause Society:

Fezolinetant Presentations

Abstract	Presentation Details

Effect of fezolinetant on moderate-to-severe vasomotor symptoms in subgroups based on hormone therapy history: pooled data from two randomized Phase 3 studies	Nanette Santoro, M.D. Oral Presentation Thursday, Sept. 28 from 4:45-5 p.m.
Effect of fezolinetant on moderate-to-severe vasomotor symptoms according to time of day: pooled data from two randomized Phase 3 studies	Genevieve Neal-Perry, M.D., Ph.D. Poster Session Thursday, Sept. 28 from 6:15-7:15 p.m.
Pooled fezolinetant safety data over 52 weeks from three randomized Phase 3 studies (SKYLIGHT 1, 2 and 4)	Risa Kagan, M.D. Poster Session Thursday, Sept. 28 from 6:15-7:15 p.m.

VMS Presentations

Abstract	Presentation Details
Treatment satisfaction among women with moderate to severe vasomotor symptoms (VMS) due to menopause and physicians who treat women with VMS in the United States	Barbara DePree, M.D. Oral Presentation Thursday, Sept. 28 from 5:30-5:45 p.m.
Prevalence and impact of vasomotor symptoms due to menopause: Canadian subgroup of the Women with Vasomotor Symptoms Associated With Menopause (WARM) study	Nese Yuksel, Pharm.D. Poster Session Thursday, Sept. 28 from 6:15-7:15 p.m.
Patient experience and management of vasomotor symptoms due to menopause: voices from the PatientsLikeMe community	Jessica Shepherd, M.D. Poster Session Thursday, Sept. 28 from 6:15-7:15 p.m.
Health disparities in prevalence of diagnosed vasomotor symptoms in women of menopausal age	Gloria Richard-Davis, M.D. Poster Session Thursday, Sept. 28 from 6:15-7:15 p.m.

About the BRIGHT SKY™ Phase 3 Program
The BRIGHT SKY pivotal trials, SKYLIGHT 1™ (NCT04003155) and SKYLIGHT 2™ (NCT04003142), enrolled over 1,000 women with moderate to severe VMS. The trials are double-blinded, placebo-controlled for the first 12 weeks followed by a 40-week treatment extension period. Women were enrolled at over 180 sites within the U.S., Canada and Europe. SKYLIGHT 4™ (NCT04003389) is a 52-week double-blinded, placebo-controlled study designed to investigate the long-term safety of fezolinetant. For SKYLIGHT 4, over 1,800 women with VMS were enrolled at over 180 sites within the U.S., Canada and Europe.

About VEOZAH (fezolinetant)
VEOZAH (fezolinetant) is a neurokinin 3 (NK3) receptor antagonist approved in the U.S. for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause. VEOZAH is not a hormone. VMS are the feelings of warmth in the face, neck, and chest, or sudden intense feelings of heat and sweating (“hot flashes” or “hot flushes”). VEOZAH works by blocking neurokinin B (NKB) binding on the kisspeptin/neurokinin B/dynorphin (KNDy) neuron to modulate neuronal activity in the thermoregulatory center of the brain (the hypothalamus) to reduce the frequency and severity of moderate to severe VMS due to menopause.

U.S. Important Safety Information

Do not use VEOZAH if you:
- have cirrhosis.
- have severe kidney problems or kidney failure.
- are taking certain medicines called CYP1A2 inhibitors. Ask your healthcare provider if you are not sure.

Before you use VEOZAH, tell your healthcare provider about all of your medical conditions, including if you:
- have liver disease or problems.
- have kidney problems.
- have any medical conditions that may become worse while you are using VEOZAH.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VEOZAH may affect the way other medicines work, and other medicines may affect how VEOZAH works.

What are the possible side effects of VEOZAH?
VEOZAH can cause serious side effects, including:
- **increased liver blood test values.** Your healthcare provider will do a blood test to check your liver before you start taking VEOZAH. Your healthcare provider will also do this blood test at month 3, month 6, and month 9 after you start taking VEOZAH.

Call your healthcare provider right away if you have the following signs and symptoms of liver problems:
- nausea

- vomiting
- yellowing of the eyes or skin (jaundice)
- pain in the right upper stomach (abdomen)

The most common side effects of VEOZAH include:
- stomach (abdominal) pain
- diarrhea
- difficulty sleeping (insomnia)
- back pain
- hot flashes or hot flushes

These are not all the possible side effects of VEOZAH. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

Call your healthcare provider for medical advice about side effects. You may report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, please see the full Prescribing Information and Patient Product Information for VEOZAH (fezolinetant).

About Astellas
Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into VALUE for patients. For more information, please visit our website at https://www.astellas.com/en.

Cautionary Notes
In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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References

[1] Utian WH. Psychosocial and socioeconomic burden of vasomotor symptoms in menopause: a comprehensive review. Health Qual Life Outcomes. 2005;3:47.

[2] Jones RE, Lopez KH, eds. *Human Reproductive Biology*. 4th ed. Waltham, MA: Elsevier, 2014:120.