Press Release

Astellas to Present VEOZAH™ (fezolinetant) Data at 2024 Annual Meeting of The Menopause Society

- Pooled analyses from two SKYLIGHT™ studies highlight impact on sleep disturbance and impairment, relationship between improvements in the frequency or severity of hot flashes and mood -

- Pooled data from three SKYLIGHT™ studies assess safety and tolerability in Hispanic/Latina women -

- Responder analysis from DAYLIGHT™study evaluates reduction in VMS frequency in women unwilling or unable to take hormone therapy -

TOKYO, September 4, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") announced that VEOZAH™ (fezolinetant), its first-in-class treatment for moderate to severe vasomotor symptoms (VMS) due to menopause, will be featured in four oral presentations during the 2024 Annual Meeting of The Menopause Society (TMS) September 10-14 in Chicago. VMS, also known as hot flashes and/or night sweats, are common symptoms of menopause.[1,2]

Marci English, Vice President, Head of BioPharma Development, Astellas
"We are thrilled to share multiple presentations at this year's Annual Meeting of The Menopause Society that continue to add to our extensive body of evidence for VEOZAH as a first in class nonhormonal treatment for moderate to severe VMS due to menopause. We are looking forward to highlighting patient-reported sleep data from our SKYLIGHT studies, as well as a new responder analysis from our DAYLIGHT study that included women who are unwilling or unable to take hormone therapy."

Fezolinetant data to be presented during the 2024 Annual Meeting of The Menopause Society include:

- Two separate pooled analyses from SKYLIGHT 1 and SKYLIGHT 2 examining improvements in patient-reported sleep disturbance and impairment (Session 1; Thursday, Sept. 12, 4:30-4:45 p.m.; Marla Shapiro, C.M.), as well as the relationship between improvements in the frequency or severity of hot flashes and mood (Top Scoring Abstract Session; Friday, Sept. 13, 1-1:15 p.m.; Genevieve Neal-Perry, M.D.).
- Data from DAYLIGHT evaluating percent reduction (≥50%, ≥75% and 100%) in frequency of moderate to severe VMS in women considered unsuitable for hormone therapy (Session 2; Thursday, Sept. 12, 5:45-6 p.m.; Marla Shapiro, C.M.).

- Pooled data from SKYLIGHT 1, SKYLIGHT 2 and SKYLIGHT 4 assessing the safety and efficacy of fezolinetant in Hispanic and Latina participants (Session 1; Thursday, Sept. 12, 4:45-5 p.m.; Genevieve Neal-Perry, M.D.).

An additional poster presentation will highlight results of a qualitative analysis designed to identify concepts and perspectives related to VMS experience among Black or African American women (Thursday, Sept. 12, 6:15-7:15 p.m.; Makeba Williams, M.D.).

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 DAYLIGHT
DAYLIGHT (NCT05033886) is a Phase 3b, randomized, double-blind, placebo-controlled, 24-week study to assess the efficacy and safety of fezolinetant in menopausal women aged 40-65 suffering from moderate to severe VMS and considered unsuitable for hormone therapy. A total of 453 women were enrolled at 69 sites in Canada, Europe and Turkey.

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.

VEOZAH can cause serious side effects, including:
- **increased liver blood test values and liver problems.** 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 monthly for the first 3 months, at month 6, and month 9 after you start taking VEOZAH or if you have signs or symptoms that suggest liver problems. If your liver blood test values are elevated, your healthcare provider may advise you to stop treatment or request additional liver blood tests.

Stop VEOZAH and call your healthcare provider right away if you have the following signs or symptoms of liver problems:
- feeling more tired than you do usually
- nausea
- vomiting
- itching
- yellowing of the eyes or skin (jaundice)

- pale feces
- dark urine
- 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 are encouraged to report negative 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.