

Astellas' Real-World Evidence Studies Provide Further Insight into Negative Impacts of Vasomotor Symptoms (VMS) Associated with Menopause

New findings to be presented at The North American Menopause Society (NAMS) 2020 Virtual Annual Meeting

TOKYO, September 28, 2020 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) today announced findings from two Real-World Evidence (RWE) studies and a qualitative sleep survey that underscore the prevalence of vasomotor symptoms (VMS) associated with menopause and the disruptive impact of these symptoms on sleep. These data will be presented during two pre-recorded oral presentations and one poster session at The North American Menopause Society (NAMS) 2020 Virtual Annual Meeting, available online starting September 28, 2020.

Vasomotor symptoms (VMS) – comprising of hot flashes and night sweats – are the most common symptoms associated with menopause^{1,2} and are often reported as the most bothersome³.

“These studies better characterize the burden of vasomotor symptoms associated with menopause and underscore the negative impacts on quality of life for women, particularly as it relates to sleep,” said Judith Nelissen, Ph.D., Vice President, Head of Health Economics and Outcomes Research (HEOR), Medical Affairs, Astellas. “At Astellas, we remain committed to creating and delivering value for women in need of new treatment options to address vasomotor symptoms.”

In a retrospective analysis of the racially and culturally diverse midlife women participating in the Study of Women’s Health Across the Nation (SWAN) database, high VMS frequency was associated with greater odds of sleep problems (i.e., difficulty falling asleep, waking early and sleep interruption) and worse sleep quality. After controlling for VMS frequency, other comorbidities, and a range of covariates, women with migraines or arthritis were also at higher risk of worse sleep. Three comorbidities were found to amplify or attenuate the association between VMS frequency and of sleep quality: diabetes, hypertension, and migraines. These findings warrant further investigation, as greater understanding may help healthcare providers better tailor treatment plans for their patients.

Results from a global prospective online survey showed 34 percent of postmenopausal women in the U.S. (mean age was 57 years) experience moderate-to-severe VMS, and 61 percent of those women experience associated sleep disturbances. Hot flashes and night sweats were shown to be among the top five most bothersome symptoms based on the Menopause-specific Quality of Life Questionnaire (MENQOL). Additionally, 47 percent of U.S. respondents had contacted their healthcare provider within the last year to discuss hot flashes and night sweats.

Results also showed an economic burden of menopause-related symptoms in terms of healthcare resource utilization and out-of-pocket costs and support the need for developing newer treatments for menopause-related symptoms.

Oral Presentations (Available On-Demand)

Title: Effect of Vasomotor Symptom Frequency and Comorbidities on Sleep Quality Among Women in Midlife: A Retrospective Analysis of the US SWAN Database (Abstract #S-10)

- Presenter: Risa Kagan, M.D., FACOG, Sutter Health, Berkeley

Title: Global Prospective Survey of Women with Vasomotor Symptoms Associated with Menopause: U.S. Findings (Abstract #S-15)

- Presenter: Robin Kroll, M.D., FACOG, Seattle Women's Health, Washington

Poster Session

Title: Qualitative Study of the Burden of Vasomotor Symptoms Associated with Menopause and Content Validity of Two PROMIS Sleep Measures in Menopausal Women (Abstract #P-6)

- Presenter: Marci English, MPH, Astellas

About Vasomotor Symptoms (VMS)

Globally, approximately 57 percent of women 40 to 64 years of age have reported the occurrence of hot flashes (also known as hot flushes) and sweating.⁴ VMS can have a considerable effect on women's comfort and sleep and can lead to anxiety, irritability, loss of productivity and depression.⁵ Hot flashes are also the most common symptom for women transitioning through menopause.⁶

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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- ⁶ Freedman RR. Menopausal hot flashes: Mechanisms, Endocrinology, treatment. *The Journal of Steroid Biochemistry and Molecular Biology*. 2014; 142:115-120. doi: 10.1016/j.jsbmb.2013.08.010.