Xenon Pharmaceuticals Showcases XEN1101 Epilepsy Program at 35th International Epilepsy Congress

September 4, 2023

New interim data from ongoing Phase 2b X-TOLE open-label extension demonstrates improvement in overall quality-of-life (QoL) when compared to baseline

Clinically important improvements seen for all patients across important subscales of Seizure Worry, Social Functioning and Medication Effects and for seizure free patients across all QoL subscales

Oral presentations showcase Phase 3 clinical trials in focal onset seizures and primary generalized tonic-clonic seizures

VANCOUVER, British Columbia, Sept. 04, 2023 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today announced a summary of its oral and poster presentations at the 35th International Epilepsy Congress (IEC) taking place in Dublin, Ireland from September 2-6, 2023.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer, stated, "The IEC meeting in Dublin provides us with another key opportunity to connect with leading epileptologists and showcase our XEN1101 Phase 3 epilepsy program, which includes our ongoing X-TOLE2, X-TOLE3, and X-ACKT clinical trials in focal onset seizures and primary generalized tonic-clonic seizures, respectively. In addition, we presented interim data from the ongoing open-label extension study from our Phase 2b X-TOLE trial, showing the long-term efficacy of XEN1101 as demonstrated by patients experiencing continued seizure reduction during the OLE and extended periods of seizure freedom, which translates into overall improvements in patients' quality of life. These new data related to quality-of-life improvements are consistent with the compelling clinical results generated to date and contribute to the growing evidence that support the promise of XEN1101 as a novel, differentiated potential treatment for patients with epilepsy."

An interim analysis (cutoff date September 22, 2022) of the ongoing X-TOLE open-label extension (OLE) study demonstrated that treatment with XEN1101 resulted in sustained monthly reduction in seizure frequency from double-blind period (DBP) baseline, with adverse events (AEs) consistent with previous results and those seen with other antiseizure medications (ASMs), and no new safety signals were identified.

Newly compiled interim data from the X-TOLE OLE focused on quality-of-life (QoL) measures as assessed using a validated tool called the Quality of Life in Epilepsy Inventory-31 (QOLIE-31) in the overall OLE group as well as a subgroup that was seizure-free (SFG) for at least 12 consecutive months at the time of the interim data analysis. The SFG consisted of 29 patients (approximately 10.5% of those enrolled in the OLE).

- The overall OLE patient group showed improvements in overall Quality of Life
- Clinically important improvements in QOLIE-31 subscales of Seizure Worry, Social Functioning, and Medication Effects were seen across all patients, with even greater improvements in the SFG
- The SFG achieved clinically important improvements in all QoL subscales assessed by the QOLIE-31
- The improvements in Medication Effects across all patients is notable as this measures the patients' perception of drug tolerability as well as the benefit of long-term seizure reduction

Dr. Christopher Kenney, Xenon's Chief Medical Officer, stated, "As we continue to amass data from our ongoing open-label extension study – with a cohort of patients now on drug for more than three years – XEN1101 has continued to demonstrate its efficacy through sustained seizure reduction. As a clinician, it is encouraging to see these QoL data, such as the improvements seen across all patients in Medication Effects, as this suggests that patients may benefit from XEN1101, perceiving it to be efficacious and generally well tolerated. Recognizing that there is a substantial need for new, efficacious, and well-tolerated antiseizure medications, we are excited to continue to advance the development of XEN1101 across multiple ongoing Phase 3 epilepsy studies."

Summary of IEC 2023 Presentations and Poster Sessions

On Sunday, September 3, 2023, Xenon hosted the following presentations at IEC 2023:

- **Poster:** "Quality-of-Life Improvements in Adults With Focal Onset Seizures Treated With XEN1101 in an Ongoing, Long-Term, Open-Label Extension of a Phase 2b Study (X-TOLE)."
- **Poster:** "XEN1101, a Novel Potassium Channel Modulator: Interim Data From an Ongoing, Long-Term, Open-Label Extension of a Phase 2b study (X-TOLE) in Adults With Focal Epilepsy."

- **Oral Presentation**: Design of Two Parallel Randomized, Double-Blind, Placebo-Controlled Phase 3 Studies to Evaluate the Safety and Efficacy of XEN1101 as Adjunctive Therapy in the Treatment of Focal Onset Epilepsy."
- **Oral Presentation**: A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Safety and Efficacy of XEN1101 as an Adjunctive Therapy in the Treatment of Primary Generalized Tonic-Clonic Seizures."

Presentations and posters will be added to the Xenon website consistent with IEC 2023 conference guidelines.

About Xenon Pharmaceuticals Inc.

Xenon Pharmaceuticals (NASDAQ:XENE) is a clinical stage biopharmaceutical company committed to developing innovative therapeutics to improve the lives of patients with neurological disorders. We are advancing a novel product pipeline of neurology therapies to address areas of high unmet medical need, with a focus on epilepsy. For more information, please visit www.xenon-pharma.com.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 and Canadian securities laws. These forward-looking statements are not based on historical fact, and include statements regarding the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN1101; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in our XEN1101 development program; and our ability to successfully develop and obtain regulatory approval of XEN1101. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events, or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical trials may not demonstrate safety and efficacy of any of our or our collaborators' product candidates; promising results from pre-clinical development activities or early clinical trial results may not be replicated in later clinical trials; our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations may be incorrect; our ongoing discovery and pre-clinical efforts may not yield additional product candidates; any of our or our collaborators' product candidates, including XEN1101, may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; we may not achieve additional milestones in our proprietary or partnered programs; regulatory agencies may impose additional requirements or delay the initiation of clinical trials; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; the impact of new or changing laws and regulations; the impact of pandemics, epidemics and other public health crises on our research and clinical development plans and timelines and results of operations, including impact on our clinical trial sites, collaborators, regulatory agencies and related review times, and contractors who act for or on our behalf; the impact of unstable economic conditions in the general domestic and global economic markets; adverse conditions from geopolitical events; as well as the other risks identified in our filings with the Securities and Exchange Commission and the securities commissions in British Columbia, Alberta, and Ontario. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

Investor/Media Contact:
Jodi Regts
Xenon Pharmaceuticals Inc.
Phone: 604.484.3353
Email: investors@xenon-pharma.com

XENON

Source: Xenon Pharmaceuticals Inc.