



## **Xgene Pharmaceutical Announces Positive Topline Results from Phase 2b Trial of XG005 Tablet for Treating the Symptoms of Osteoarthritis of the Knee**

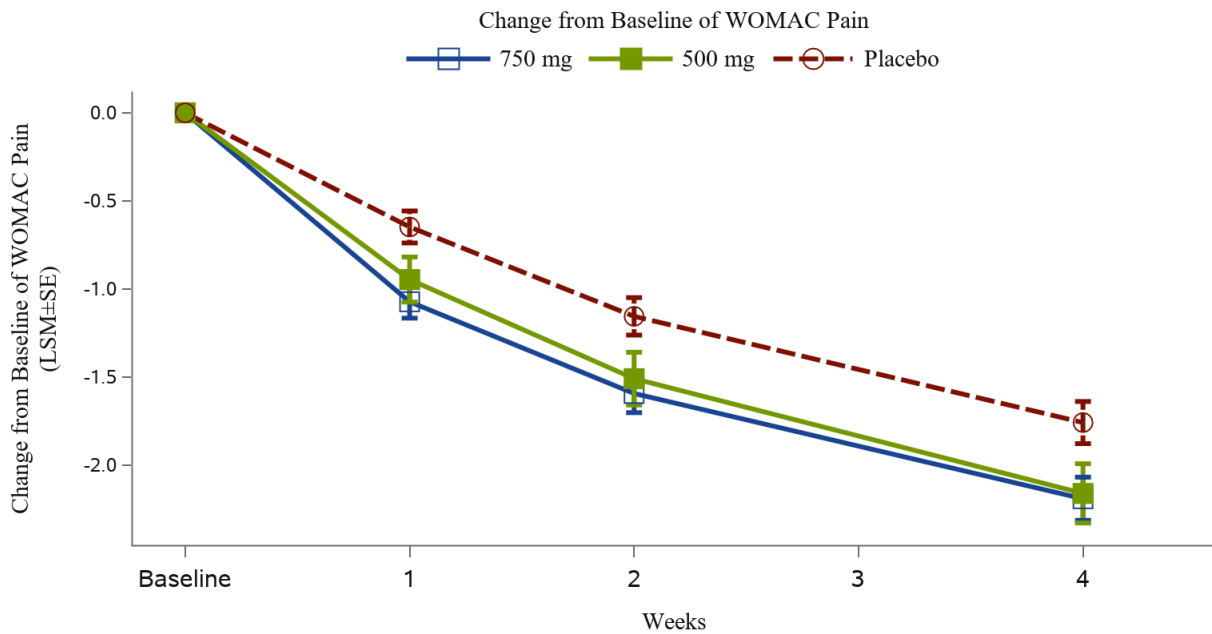
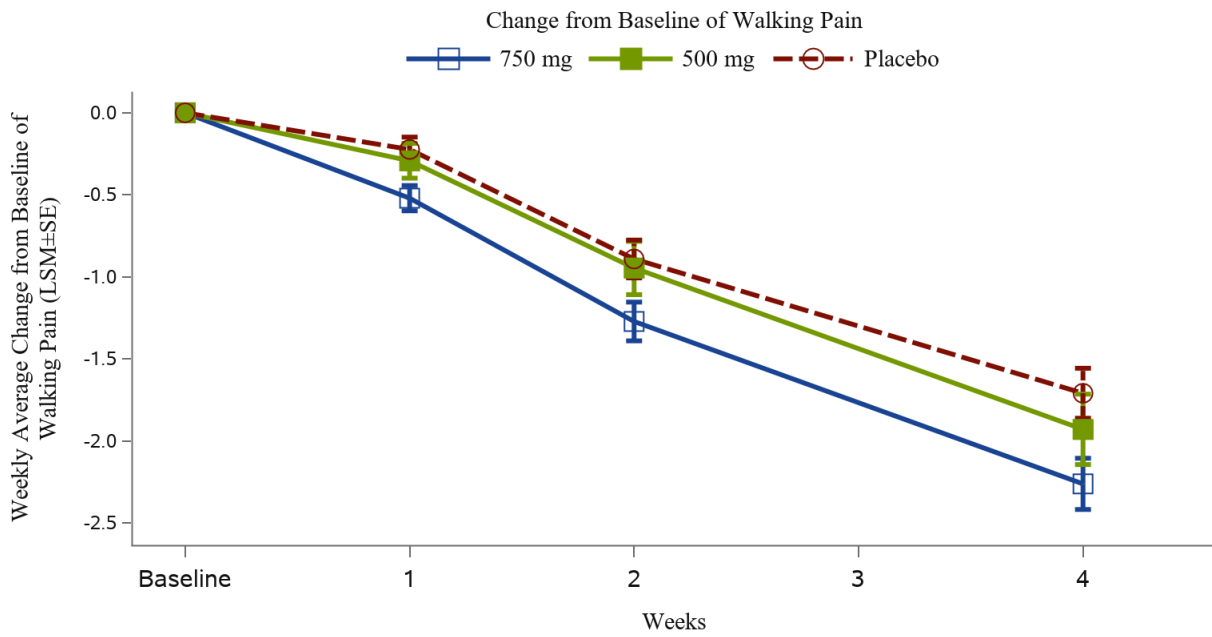
- *The Primary Efficacy Endpoint of pain improvement from baseline was statistically significant for the 750 mg arm compared to placebo at Week 4 in mITT population (P=0.0055). The result was consistent with ITT and PPS analysis populations and was confirmed with observed data and multiple input sensitivity analyses –*
- *All Key Secondary Efficacy Endpoints achieved statistical significance compared with placebo for both 500 mg and 750 mg arms, including WOMAC Pain subscore and KOOS Pain subscore –*
- *Other Statistically Significant Efficacy Endpoints at Week 4 for 750 mg group versus placebo included WOMAC Stiffness, Function and Total scores (also positive for 500 mg group); KOOS subscores; Sleep Interference Score; both Patient and Clinician Global Impression of Change (PGIC) (also positive for 500 mg group); OMERACT-OARSI responder rate and proportion of patients with  $\geq 30\%$ , 50% or 70% improvement of Walking Pain –*
- *XG005 was safe and well tolerated–*

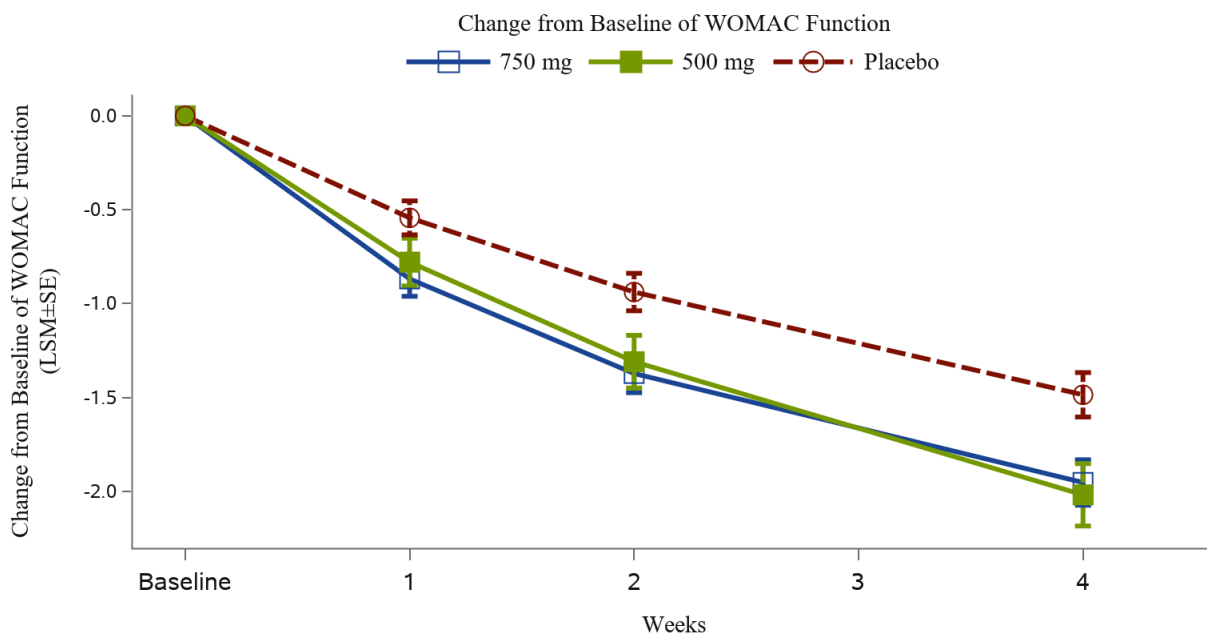
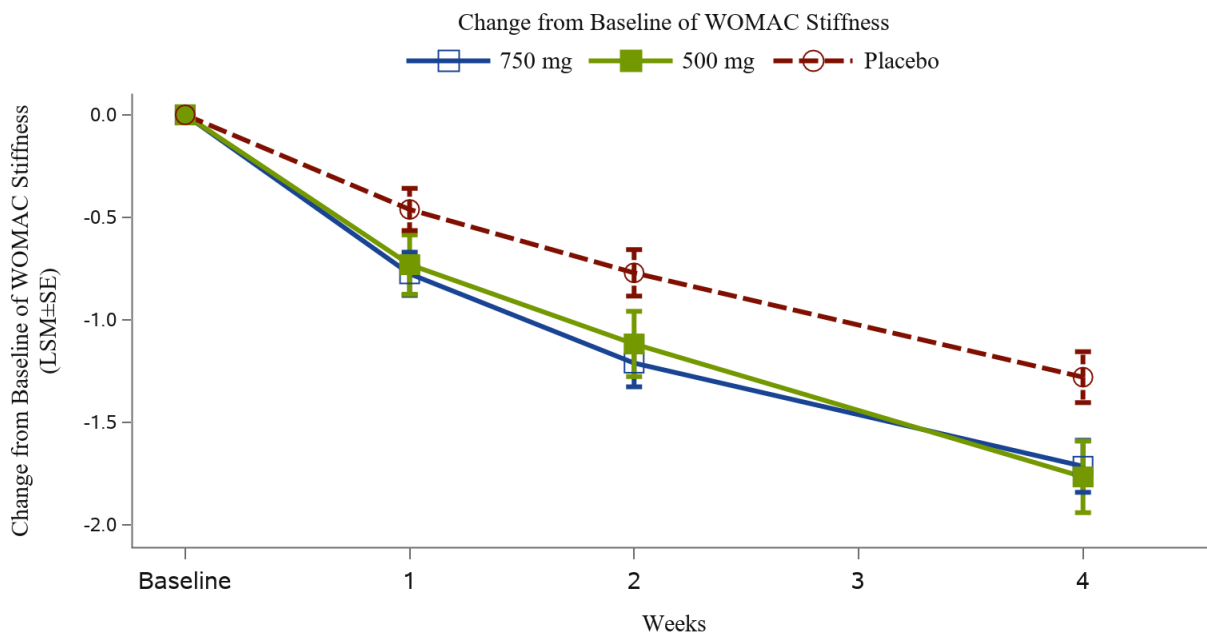
Shanghai, China, August 8<sup>th</sup>, 2024: Xgene Pharmaceutical today announced the positive results of a multiple-center, placebo-controlled, dose-ranging Phase 2b study (registration number: 2021LP01217) in patients with painful knee osteoarthritis (OA), evaluating the safety and efficacy of the XG005 oral tablet.

XG005 is a new, non-opioid, investigational chemical entity with dual action in treating both nociceptive and neuropathic pain. The 750 mg, 500 mg or placebo dose was administered twice a day (bid) for 4 weeks to patients with painful knee due to OA. The study was conducted at multiple sites in China. A total of 331 OA patients suffering moderate to severe pain of the knee, with Kellgren-Lawrence grade of II-III, were enrolled in the trial. The drug was well tolerated with an acceptable safety profile. There were no drug-related serious adverse events.



The primary efficacy endpoint and WOMAC pain, stiffness and function sub-scores are shown in the figures below.





Professor Li ZhanGuo, the lead principal investigator from Beijing Renmin Hospital of Beijing University commented, “Thanks to the enormous efforts from our team of investigators. We are very pleased with the outcomes of this Phase IIb trial. The data showed that XG005 can not only significantly reduce arthritis pain, but also improve functions. It is a promising additional means to treat OA patients without resorting to opioids”.

“We are extremely encouraged by the robustness of the study results; the broad efficacy measures consistently supported each other, showing that XG005 had dose-dependent pain reduction accompanied with improvements in joint stiffness and function along with prompt onset of effect. Currently, no pain treatment for OA has earned the joint stiffness or function improvement on an



approved label. The compelling effect of XG005 may distinguish it from other currently available therapies and further benefit patients.” said Leon Jiang, Chief Medical Officer at Xgene Pharmaceutical.

“There is a substantial need for safer, more innovative treatment options for osteoarthritis, as many patients are unable to get sufficient relief with currently available medicines due to intolerable side effects. We are pleased that the results from this trial showed the excellent therapeutic effect of XG005, with the potential to be a better treatment option compared to current therapies,” said Gene Hsu, CEO of Xgene. “Xgene is proud to continue its efforts on this unique product aiming for various chronic pain conditions, moving forward with great confidence.”

### **About Osteoarthritis**

Osteoarthritis (OA) is a painful, irreversible, and debilitating chronic degenerative joint disease affecting approximately 595 million people globally. Cases of OA are projected to increase 49-95% for various joints by 2050 as population ages (GBD Osteoarthritis Collaborators. Global, regional, and national burden of osteoarthritis, 1990–2020 and projections to 2050: a systematic analysis for the Global Burden of Disease Study 2021. *Lancet Rheumatol* 2023; 5: e508–22). The direct medical costs of OA in US are estimated at \$72 billion. The economic burden of OA accounts 1-2.5% of GDP in countries with established market economies (Leifer VP, Katz JN, Losina E. The burden of OA-health services and economics. *Osteoarthritis and Cartilage* 30(2022)10e16).

### **About XG005**

XG005, a novel molecule possesses dual-acting functions of anti-inflammatory and anti-neuropathic pain therapeutic potential. It is a potential first-in-class, non-opioid oral treatment in development for the treatment of chronic and acute pain conditions.

A pivotal trial of XG005 on acute surgical pain is rapidly enrolling in the USA, and a Phase 2 trial of XG005 on cancer-induced bone pain is also ongoing in Mainland China and Taiwan.

### **About Xgene Pharmaceutical: *Transforming Medicine for Better Lives***

At Xgene, we apply new clinical findings, science, and innovative technology to bring therapies to patients to extend and significantly improve their lives. We strive for quality, safety and value in our new products. Our goal is to deliver the world's best medicine to patients worldwide. Xgene’s drug discovery areas include pain and CNS conditions focusing research on finding treatments and cures to unmet medical needs. We collaborate with health care providers, governments, and local communities to identify patient needs and deliver reliable, affordable medicines around the world. Visit our website at [www.xgenepharm.com](http://www.xgenepharm.com).