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A Prospective Study in More Than 1,000 Osteoporosis Patients Concluded That Binosto® (Buffered Soluble Alendronate) May Increase Patient Satisfaction, Long-Term Adherence and Therefore Efficacy

FREIENBACH, Switzerland–(BUSINESS WIRE)–
Corporate IR Press Release

In a newly published international multicenter study[1] in over 1,000 osteoporosis patients treated with Binosto® and followed for 12 ± 3 months,

- Binosto was well tolerated
- Treatment persistence was high
- Mean overall compliance was high too
- Patient satisfaction remained at approximately 90%

EffRx Pharmaceuticals SA, a commercial-stage pharmaceutical company that commercializes niche and orphan medicines in Switzerland and Europe, announces the full paper publication of the GastroPASS Study Results of Binosto® (buffered soluble alendronate) in *JBMR® Plus*, a premier peer-reviewed medical journal. Prof. Salvatore Minisola will present the study results as an oral communication (OC 19) at the WCO-IOF-ESCEO[2] virtual congress on August 28, 2021 at 11:40 am.

GastroPASS was a prospective, observational, multicenter, multinational, single-arm, post-authorization safety study. The study enrolled 1,084 postmenopausal women with osteoporosis, newly prescribed Binosto® and naïve to bisphosphonate therapy. At baseline, 31% of enrolled patients reported a medical history of gastrointestinal (GI) tract conditions that did not exclude study participation. Patients were followed for 12 ± 3 months. The primary objective was to evaluate the incidence of upper GI adverse events and medication errors during treatment. Secondary aims were to evaluate persistence, discontinuation and reasons for discontinuation.

The cumulative incidence of all upper GI AEs related to Binosto® observed during the duration of the study was low at 9.6%. The study authors stated that "*the incidence of upper GI AEs in this "real-world" study were found to be lower than that observed in alendronate-treated groups from randomized controlled trials with a duration of 12 months.*" Also, the incidence rate of individual gastric AEs related to Binosto was low (ranging from 0 to 2.1 per 1,000 patients/month) and decreased over the three follow-up periods of the study. No events for gastric ulcer, gastric perforation, gastric hemorrhage, and gastric stenosis were observed.

Treatment persistence reported in this study was high at 79.7% at 12 ± 3 months. These results are well in line with the recently published findings by Giusti et al.[3] Mean overall compliance was high, too, at 92.8 using the Morisky-Green questionnaire and 94.8 based on the number of tablets missed.

Patient satisfaction and preference were also high, at approximately 90%, both in terms of how easy it was to take Binosto® and how much easier it was to take Binosto compared with other medications.

"Prof Minisola et al have conducted an interesting study. Results are interesting and needed, considering that alendronate is still a very important medication. (…) Oral bisphosphonates are considered the first line treatment in patients after fragility fractures.

The present data are encouraging in terms of low prevalence of GI side effects. (…) To prescribe medications with low rate of side effects is important also during the pandemic, given the restrictions and limited access to osteoporosis clinics.", commented one of the independent reviewers of *JBMR Plus*.

Overall, post-menopausal women with osteoporosis treated with Binosto® (buffered soluble alendronate) in a real-world setting experienced few upper GI AEs. In addition, they had a low discontinuation and high compliance compared to other formulations, suggesting that buffered soluble alendronate may increase patient satisfaction and therefore long-term adherence and efficacy.

"Based on my experience as the PI and first author of the pivotal trial on alendronate, a first-line treatment in osteoporosis, I believe that this study was needed and the results are relevant to provide good evidence for this alternative formulation of alendronate. The low incidence of upper GI AEs, the low discontinuation rate and the high compliance observed in the study reinforce previous clinical data regarding Binosto. These results offer confidence that Binosto could lead to increased patient satisfaction and therefore better long-term adherence and efficacy than pill forms." commented Prof. Dennis M Black, study co-author.

[1] The full paper publication can be found at: *JBMR® Plus*

[2] World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases

[3] Giusti A et al. A novel effervescent formulation of oral weekly alendronate (70 mg) improves persistence compared to alendronate tablets in post-menopausal women with osteoporosis. Aging Clin Exp Res 2021; https://doi.org/10.1007/s40520-020-01777-9.

About *JBMR® Plus*

JBMR® Plus is the premier open access journal of the American Society for Bone and Mineral Research (ASBMR). A companion to internationally recognized title *Journal of Bone and Mineral Research*, *JBMR® Plus* aims to improve global musculoskeletal health by publishing innovative research covering endocrinology, geriatrics, orthopedics and rheumatology.

About EffRx Pharmaceuticals

EffRx Pharmaceuticals is a commercial-stage pharmaceutical company focused on the late stage development and commercialization of prescription medications for niche and orphan indications. The business model is centered around providing superior clinical and commercial value propositions for physicians, payers and patients.

EffRx's go-to-market competence is proven by the development, launch and successful expansion of Binosto® in highly competitive markets.

EffRx pro-actively seeks in-licensing opportunities for Europe in niche therapeutic areas, with a primary interest for rare diseases, where EffRx has received an orphan drug designation (ODD) from the FDA for a pipeline asset.

About Binosto®

Binosto® (Buffered Soluble Alendronate) is a first-line treatment of postmenopausal osteoporosis patients that is associated with preferable pharmacologic properties translating into clinical benefit for patients. Alendronate as recommended by guidelines is a first line treatment for postmenopausal women with osteoporosis. Alendronate 70 mg tablet once weekly is the most commonly used bisphosphonate but adherence is problematic, with >50% discontinuing treatment within the first year. To address this, Binosto®, a novel buffered soluble alendronate 70 mg effervescent tablet formulation was specifically developed to improve GI tolerability and adherence to treatment.