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TARSA THERAPEUTICS PRESENTS META-ANALYSIS AT ASBMR 2013 SHOWING CALCITONIN DOES NOT APPEAR TO BE ASSOCIATED WITH INCREASED RISK OF CANCER

—Study is First to Analyze All Relevant Clinical Trials of Oral and Intranasal Calcitonin in Women—

—Results are Consistent with Calcitonin's 30-Year Safety Record and the Lack of Biological Plausibility—

BALTIMORE, MD and PHILADELPHIA, PA – October 7, 2013 — Tarsa Therapeutics, Inc. today announced that it presented a new meta-analysis showing that salmon calcitonin does not appear to be associated with an increased risk of cancer in postmenopausal women. The meta-analysis was conducted using data derived from approximately 11,000 women in 24 randomized, controlled calcitonin trials that included reporting of adverse events. The meta-analysis yielded an odds ratio close to unity with a narrow bound on the error of estimation, suggesting that calcitonin does not appear to be associated with an increased risk of cancer.

The data were presented in a plenary poster session at the 2013 ASBMR Annual Meeting.[1] Tarsa is developing an oral calcitonin tablet for the treatment and prevention of post-menopausal osteoporosis.

In 2012, the European Medicines Agency withdrew calcitonin nasal spray from the market and limited the duration of use of other calcitonin products, due to a purported association with cancer. In early 2013, similar data were the topic of a joint meeting of the FDA's Advisory Committee for Reproductive Health Drugs and its Drug Safety and Risk Management Advisory Committee. At that meeting Tarsa representatives highlighted that:

- Despite 30 years of global use, no post-marketing surveillance reports from any regulatory authority have ever linked calcitonin with cancer.
- A previous meta-analysis conducted by Novartis[2] did not include data from more recent clinical trials of oral calcitonins, including Tarsa's oral calcitonin product.
- Given that formal calcitonin carcinogenicity and mutagenicity tests in animals have all been negative and that cancer is biologically diverse, no plausible mechanism has been identified that could explain a putative increased cancer risk.

"There are only a few classes of agents available to treat osteoporosis, and the fact that millions of patients are currently going untreated, or opting out of treatment, underscores the need for more therapeutic choices," noted Dr. David Krause, Chief Medical Officer of Tarsa. "Calcitonin has been shown to have a modest but consistent positive effect on bone mineral density at the lumbar spine, and this more comprehensive meta-analysis confirms our earlier research showing that calcitonin does not appear to be associated with an increased risk of cancer."

At the 2012 ASBMR Annual Meeting, Tarsa presented an analysis that concluded there was no carcinogenicity signal in the two one-year long trials of its oral calcitonin, which enrolled almost 700 women.[3]

In a Phase III global, randomized, double-blind trial in postmenopausal women with osteoporosis, known as the ORACAL trial, Tarsa's once-daily oral calcitonin demonstrated superiority to both placebo and nasal calcitonin spray in increasing bone mineral density at the lumbar spine after 48 weeks. In the trial, the safety profile of oral calcitonin did not substantially differ from nasal calcitonin or placebo. The trial results were published in the *Journal of Bone and Mineral Research*.[4]

Tarsa is preparing to file an NDA in 2014 for the use of its oral calcitonin in the treatment of postmenopausal osteoporosis.

Studies for inclusion in the new meta-analysis were identified from regulatory documents and the scientific literature and also included Tarsa's two long-term clinical trials of its oral calcitonin product. The meta-analysis was prepared under the supervision of lead author Dr. George A. Wells and Dr. Jonathan Chernoff. Dr. Wells is a Professor in the Department of Epidemiology and Community Medicine at the University of Ottawa and is a Professor in the Department of Medicine and a Senior Scientist at the Ottawa Health Research Institute. Previously, Dr. Wells was Chief of the Biometrics Division at Health Canada's Laboratory Centre for Disease Control. Dr. Chernoff is Senior Vice President, Chief Scientific Officer and holds the Stanley P. Reimann Chair in Oncology Research at the Fox Chase Cancer Center.

1. GA Wells, J Chernoff, JP Gilligan et al. Does Calcitonin-Salmon Cause Cancer? Presented at ASBMR 2013 Annual Meeting, Plenary Poster Session, 5:45 pm, Oct 4, 2013, Discovery Hall-Hall C.

2. Heep M et al. Calcitonin Use and Risk of Malignancy: A meta-analysis of 17 rsCT in patients with osteoporosis. Presented at ASBMR 2012 Annual Meeting. Abstract 1234, October 15, 2012.

3. D Krause MD, NAS Hernandez LPD, M Vitagliano et al. "One Year Use of Oral Recombinant Salmon Calcitonin (rsCT) Is Not Associated with Increased Risk of Cancer. Presented at ASMBR 2012 Annual Meeting, Presentation No: LB-MO17, Oct 15, 2012.

4. N Binkley, M Bolognese, A Sidorowicz-Bialynicka et al. A Phase 3 Trial of the Efficacy and Safety of Oral Recombinant Calcitonin: The Oral Calcitonin in Postmenopausal Osteoporosis (ORACAL) Trial. J Bone Miner Res. 2012, 27:1821–1829.

The American Society for Bone and Mineral Research 2013 Annual Meeting is being held October 4-7, 2013 in Baltimore, MD. For more information, visit: www.asbmr.org/annual-meeting.

About Tarsa Therapeutics

Tarsa is developing a novel oral formulation of calcitonin for the treatment and prevention of postmenopausal osteoporosis. This product has the potential to be the first approved oral calcitonin, a natural hormone with a long history of safety and efficacy as an osteoporosis therapy. Tarsa is based in Philadelphia, PA. For more information, visit www.tarsatherapeutics.com.