

Brickell Biotech Secures Exclusive World-Wide Rights to a Novel Class of RORy Inhibitors for Psoriasis and Other Autoimmune Diseases

Further strengthens Brickell's pipeline of new molecular entities for skin diseases

MIAMI--(BUSINESS WIRE)-- Brickell Biotech, Inc. (Brickell), a clinical-stage pharmaceutical company focused on the development of innovative and differentiated therapeutics to satisfy medical needs in the global dermatology marketplace, today announced that it has secured the exclusive world-wide rights to a series of novel retinoic acid-related orphan nuclear receptor gamma (RORy) inhibitors from Orca Pharmaceuticals (Orca) and New York University (NYU). This chemical series is based on intellectual property emerging from the laboratory of Professor Dan Littman, MD, PhD, the Helen L. and Martin S. Kimmel Professor of Molecular Immunology and Howard Hughes Medical Institute (HHMI) Investigator at NYU School of Medicine.

Under the terms of the agreement, Brickell will assume the responsibility for the continued research and development of these RORy inhibitors, initially targeting the topical treatment of psoriasis, an inflammatory skin condition that affects over 9 million individuals in the U.S. (approximately 3% of the U.S. population).

Patricia Walker, M.D., Ph.D., President and Chief Scientific Officer at Brickell said, "We are excited about this new agreement, which further demonstrates Brickell's commitment to the development of new molecular entities targeting well-known mechanisms of action in the field of medical dermatology. RORy inhibition targets the pathway of a validated cytokine (IL-17) that has been implicated in the pathogenesis of psoriasis. Monoclonal antibodies targeting IL-17 have recently shown significant efficacy in the treatment of psoriasis, and we are very encouraged about the opportunity to develop a topically applied, potent and selective small-molecule therapeutic targeting this pathway."

RORy plays a key role in the immune system. It is involved in converting certain immune cells into pro-inflammatory Th17 cells, which produce cytokines (such as IL-17) that result in inflammation in living organisms. RORy inhibitors can help decrease inflammatory conditions by reducing the formation of Th17 cells as well as the release of pro-inflammatory cytokines. This mechanism is believed to have potential against a wide range of autoimmune diseases, such as psoriasis, inflammatory bowel disease, arthritis and multiple sclerosis.

"This announcement is the latest in a series of agreements for Brickell that strengthen the company's position as a global leader in dermatological drug development," said Charles Stiefel, Chairman, Board of Directors, Brickell. "With this latest transaction, our pipeline now consists of five product candidates, including potential novel therapeutics for hyperhidrosis (excessive sweating), atopic dermatitis, allergic contact dermatitis, acne and psoriasis."

The company expects to receive data from its Phase 2b clinical trial in 190 subjects with axillary (underarm) hyperhidrosis in early 2016.

About Brickell Biotech

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated therapeutics for the treatment of skin diseases. Our <u>management team</u> and <u>board of directors</u> have extensive experience in product development, having served in leadership roles at several pharmaceutical and successful start-up companies. Our strategy is to leverage this experience to in-license, acquire, develop and commercialize products that we believe can be successful in the global dermatology marketplace. For more information, visit <u>www.brickellbio.com</u>.

About Orca Pharmaceuticals

Orca Pharmaceuticals is a company based in Oxford, UK developing novel therapeutics for the treatment of chronic inflammatory diseases. Orca has an advanced medicinal chemistry program that has produced different chemical series targeting both oral and topical inhibitors of RORy. For more information, visit www.orcapharmaceuticals.com.

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