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SK gets rights to sell TheraVida urinary drugs

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Singapore: TheraVida and SK Chemicals announced the execution of a license agreement for two of TheraVida's proprietary combination drug product candidates, THVD-201 and THVD-202. The agreement grants SK Chemicals exclusive rights to develop and commercialize THVD-201 and THVD-202 in South Korea for the treatment of overactive bladder (OAB) and urge urinary incontinence (UUI).

THVD-201 is a proprietary twice-daily (BID) formulation of tolterodine and pilocarpine that is designed to treat OAB and UUI with reduced dry mouth side effects frequently associated with currently available treatments. THVD-201 has successfully completed phase I and phase II development in international clinical trials. THVD-202 is a proprietary once-daily (QD) formulation of tolterodine and pilocarpine that is completing pre-clinical development.

According to the agreement, SK Chemicals is responsible for costs associated with the manufacturing, phase III clinical development, regulatory approval, and commercialization of THVD-201 in South Korea. SK Chemicals is also responsible for clinical development, approval, and commercialization of follow-on product THVD-202 in the territory. In return for the exclusive license to THVD-201 and THVD-202 in South Korea, TheraVida shall receive milestone payments and a royalty on net sales of the products by SK Chemicals.

In a phase II randomized, double-blind, multiple-crossover clinical trial with placebo and active controls, twice-daily THVD-201 demonstrated statistically significant improvements in OAB and UUI symptoms over placebo control, with efficacy comparable to twice-daily Detrol (tolterodine). THVD-201 was well tolerated and exhibited statistically significant and clinically meaningful

improvements in saliva production and dry mouth side effects, as compared to active control Detrol. TheraVida intends to conduct additional international clinical studies of THVD-201 and THVD-202 in patients with OAB and UUI.

Mr In- Serk Lee, CEO, SK Chemicals Life Science Business Group, "SK Chemicals is pleased to collaborate with TheraVida on the development, commercialization, and marketing of THVD-201 and THVD-202 in South Korea for the treatment of OAB and UUI. We believe THVD-201 has demonstrated a highly differentiated clinical profile, relative to tolterodine, which has been confirmed by an international Phase 2 clinical trial.

"THVD-201 has the potential to provide a new and unique treatment option for patients in South Korea. Our collaboration with TheraVida and access to these new products complements our Mvix products and the commitment by SK Chemicals to building our urology franchise, and developing products that improve the quality of life, such as Ginexin, Trast, Mvix, and others," added Mr Lee.

Dr Roger Flugel, CEO, TheraVida, said that, "TheraVida is enthusiastic about working in partnership with SK Chemicals, one of the leading pharmaceutical companies in South Korea, on the development and commercialization of THVD-201 and THVD-202. THVD-201 and THVD-202 have the potential to offer significant improvement in dry mouth side effects and better efficacy over current standard-of-care therapies for OAB and UUI. We believe these products can ultimately increase the overall tolerability, compliance, and satisfaction for patients suffering from these conditions."