Hyftor™ (sirolimus) – New drug approval

- On March 22, 2022, the FDA approved Nobelpharma's Hyftor (sirolimus) topical gel, for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older.

- The efficacy of Hyftor was established in a randomized, double-blind, vehicle-controlled study conducted in 62 Japanese adults and pediatric patients 6 years of age and older with facial angiofibroma associated with tuberous sclerosis. Patients applied Hyftor or vehicle twice daily to the skin of their face for 12 weeks. The efficacy was assessed based on the composite improvement from baseline in size and redness of facial angiofibroma. An assessment of 'Improved' was defined as at least a 50% reduction in the size and a 2-level reduction in redness and an assessment of 'Markedly Improved' was defined as at least a 75% reduction in the size and a 3-level reduction in redness.

    — A total of 23% of Hyftor-treated patients vs. 6% of vehicle-treated patients were improved or markedly improved at 12 weeks.

- Warnings and precautions for Hyftor include hypersensitivity reactions, serious infection, malignancy, hyperlipidemia, interstitial lung disease/non-infectious pneumonitis, immunizations, embryo-fetal toxicity, and male infertility.

- The most common adverse reactions (≥ 1%) with Hyftor use were dry skin, application site irritation, pruritus, acne, acneiform dermatitis, ocular hyperemia, skin hemorrhage, and skin irritation.

- Hyftor should be applied to the skin of the face affected with angiofibroma twice daily in the morning and at bedtime.

    — The maximum recommended daily dosage is: 600 mg (2 cm) for pediatric patients 6 to 11 years of age and 800 mg (2.5 cm) for adults and pediatric patients 12 years of age and older.
    — If symptoms do not improve within 12 weeks of treatment, the need for continuing Hyftor should be reevaluated.

- Nobelpharma's launch plans for Hyftor are pending. Hyftor will be available as a 0.2% topical gel.