

- **Sirolimus for topical use: Dermatology**

- Original (collaboration with Osaka Univ.) topical formulation
- Indication: Skin lesions associated with tuberous sclerosis (TSC)
- Angiofibroma: one of skin lesions specific to TSC
 - Commonly developed in central area of face including nose, nasolabial sulcus and cheek (symmetrical)
 - Only surgical excision and laser therapy formerly available
- Ca. 10,000 TSC patients in Japan
- Basic Research / Phase I/II (IIT) completed by Osaka University
- Oct 2015: Phase III / Extended Trial started by Nobelpharma Co., Ltd.
- Oct 2015: 1st SAKIGAKE* designation
- Dec 2015: Orphan drug designation
- Oct 2017: Japanese NDA filed
- Mar 2018: Approved in Japan
- May 2018: National Health Insurance listed
- Jun 2018: Launch in Japan

*SAKIGAKE: Fast-track review system to promote R&D in Japan aiming at early practical application for innovative pharmaceutical products/medical devices/regenerative medicines