TAHO Pharmaceuticals
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# Proven technology for transdermal patches and oral thin films

**The first ondansetron orally dissolving film (ODF) has been approved in Japan, validating TAHO's platform technology from prototype to commercial product.**

Transdermal patches and ODFs can enhance the safety and efficacy profiles of conventional oral or injection formulations, as they bypass first-pass metabolism and provide more consistent plasma levels of the active pharmaceutical ingredient (API). Easy to carry and simple to apply or take, patches and ODFs can also improve compliance and offer greater convenience for patients and their caregivers.

TAHO Pharmaceuticals is a specialty pharmaceutical company that is improving the administration and efficacy of existing oral or injectable drug compounds by creating new formulations with its proprietary drug delivery systems. The company focuses on products that could improve quality of life for groups of patients who may experience difficulties in taking their medication, such as geriatric and pediatric patients, as well as ease the burden on caregivers.

"By converting existing drugs into transdermal patches or oral thin films, we are also able to provide a new drug product with a longer market life and market exclusivity," said Milky Kao, business development manager at TAHO. "These products also require fewer clinical trials and benefit from accelerated development times."

Founded in 2010 in Taipei, Taiwan, TAHO has developed a pipeline of projects for central nervous system (CNS) disorders and oncology support areas where there is potential to bring maximum benefit to patients. The company's lead product, a proprietary anti-emetic ODF, recently became the first anti-emetic ODF to be approved in Japan.

## Transepithelial delivery system

TAHO's proprietary transepithelial delivery system (TDS) platform has been designed to deliver drug compounds directly into the bloodstream via the skin (transdermal) or the mouth (transmucosal). The TDS comprises a proprietary biomaterial coating, which controls release of the API, and an absorption enhancer.

"We work with special polymers that encapsulate the API and then combine these with other polymers to control the release of the API into the body," said Catherine Lee, director of the TAHO Pharmaceuticals Business Division. "We can control the API release profile into the bloodstream through the skin from patches, or via the mucosal membrane from oral thin films."

TAHO's transdermal patches feature an innovative 'drug-in-adhesive' design with enhanced drug loading, good adhesion and no or low residues. The patches are also designed to reduce skin irritation, enhance the permeation rate of the API, and increase stability.

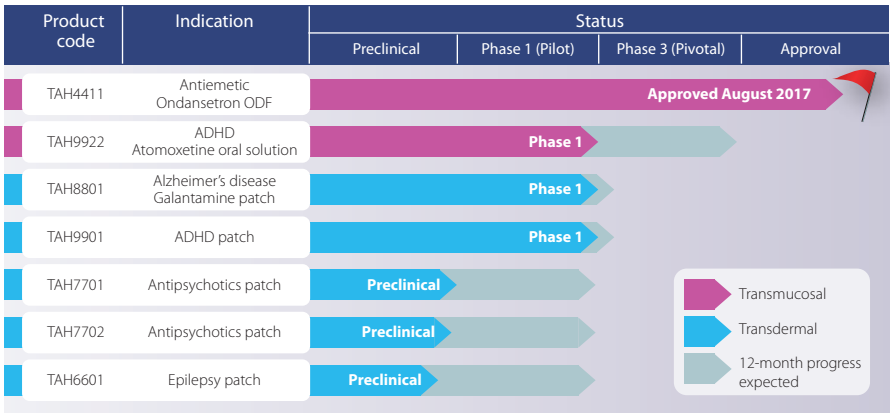


**Figure 1: Major products in the TAHO pipeline.** TAHO's products improve the delivery of existing drugs and target the fields of oncology and CNS. PMDA, Pharmaceuticals and Medical Devices Agency.

The proprietary ODFs also feature an innovative 'drug-in-polymer' design with enhanced drug loading and no brittleness, as well as enhanced stability and tension strength and good taste-masking. The process results in a very fine film that can melt as soon as it is placed in the mouth, without the need for water. "Our ODF formulations can help to improve patient compliance, especially for older patients and for children, as there is no risk of choking and the patient is not able to spit out their medication," said Lee.

TAHO's ODF is suitable for either immediate delivery of the API in the form of an oral or sublingual film or extended-release delivery in the form of a buccal or gum film. Drugs with a single API, as well as drug combinations, can be converted into ODF formulations.

## Japan approves first Ondansetron ODF

TAHO is developing a pipeline of products (**Fig. 1**) and several projects are now ready for out-licensing.

The company's lead product is a patient-friendly ODF formulation of a selective serotonin 5-HT3 receptor antagonist for the treatment of chemotherapy-induced nausea and vomiting. Study data show that the new formulation is bioequivalent to the Zofran immediate-release tablet (developed by Novartis), and in August 2017 it received marketing approval in Japan under the name "ondansetron OD film" (GFP).

TAHO is also developing products for CNS disorders, including new formulations for drugs to treat Alzheimer's disease and attention deficit hyperactivity disorder (ADHD). For example, TAH8801 is a daily-patch formulation of an acetylcholinesterase inhibitor that is being developed for Alzheimer's disease. Data from healthy volunteers have shown that the pharmacokinetic profile of TAH8801 (8 mg for 24 hours) is comparable to that of Reminyl (galantamine hydrobromide) (8 mg prolonged-release capsule). The patch can be self-administered by the patient and offers stable delivery of the API with fewer gastrointestinal side effects compared with the Reminyl oral capsule. A patent has been granted in multiple countries.

TAH9901—a flexible-wear patch for the treatment of ADHD—has also been tested in pilot pharmacokinetic studies, which showed that it is bioequivalent to Daytrana (methylphenidate transdermal system). TAHO's formulation has a higher penetration rate than Daytrana, which means the patch benefits from a lower residual methylphenidate content.

## Partnering opportunities

TAHO is currently seeking in-licensing and marketing partners or codevelopment partnerships, and is also open to contract development opportunities. "We already have a track record in successful delivery of contract development projects," said Lee. "We were able to finish a project to develop a formulation in just nine months, which is quite impressive, because a two-year minimum timeline is usually needed to develop a patch product."

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