

Young Kweon Choi - Founder, Chairman & CEO, iCure, South Korea



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iCure is a Korean company applying its advanced transdermal delivery technology to pharmaceuticals and dermo-cosmetics. The company has developed the first-ever transdermal patch for donepezil to reach Phase III clinical trials. Its CEO, Young Kweon Choi, shares his plans for this novel pharmaceutical product, as well as the company's line of dermo-cosmetics, explains what makes iCure's technology superior to that of its competitors, and showcases his ambition to become a global leader in the field of transdermal technology.

Prior to founding iCure, you mostly worked in research positions in academia and industry. What gave you the confidence to make the transition from the lab to the boardroom?

During my PhD years at the University of Utah, I always had the desire to implement the ideas in my mind that would contribute to society. However, I felt I needed broader insight in regard to the business administration to operate my own business. While I was the principal researcher at the Department of Drug Delivery Systems in Samyang Pharmaceutical, I accumulated experiences in both drug delivery research and team management. When I had acquired enough business acumen to feel confident enough to launch my own company, I transitioned myself from the researcher to the founder of iCure.

How would you define iCure's core business?

The core business of iCure is based on 'Cure & Care' solution through the skin. We offer our own technology platform in both pharmaceutical and dermatological fields.

In Asia, patches for relieving localized muscle and joint pain, also known as plasters, are commonly used. Therefore, few Asian companies have focused on developing patches for systemic drug delivery. In the US and Europe, many well-known established companies develop systemic drug delivery patches. The goal of iCure is to be the pioneer transdermal patch manufacturer in Asia and ultimately become the global leader in the field. Currently, we are targeting to develop patch medication for CNS diseases in priority with higher compliance and fewer side effects than existing medication.

We not only leverage our transdermal technology to develop improved drugs but also started the cosmeceutical business in alignment with the TDDS through skin. We are offering ODM (original design manufacturer) / OEM (original equipment manufacturer) services to a variety of local and global big companies as our major clients. Our USD 30 million total revenue is split almost equally between our pharmaceutical and dermo-cosmetic business lines.

Thanks to our specialty in biopharma with IMD (Incrementally Modified Drugs) patches and success in the cosmetic business, we were able to pass the KOSDAQ's technological assessment and go public last year.

What are your most promising R&D programs?

Our expertise lies in the development of transdermal patches for systemic delivery, treatments against CNS disorders, although we also tackle other treatment areas. Our most promising and advanced R&D program is the first-ever transdermal patch for donepezil, the most commonly used oral medication against Alzheimer's disease (AD) in the world. In fact, donepezil's successful development was a critical factor in the decision of financial regulators to allow iCure's IPO. Despite the fact that the number of patients is doubling every 5 years, 99.6 percent of the attempt to develop new drugs have been failed. In the face of multiple adversities, we are currently undergoing global clinical trial phase III in partnership with a global CRO in four countries (Australia, Korea, Malaysia and Taiwan) for Korean FDA approval. We will perform clinical trial phase I in the US this year to penetrate the global market as well.

Multi-day transdermal patches for AD present many advantages compared to the common oral dosage form. Given that memory deficit is one of the main symptoms of AD, a multi-day transdermal patch can enhance patient compliance and quality of life with patch-type visualized treatment and decreased the frequency of administration. The most significant advantage of donepezil patch is to minimize common adverse reactions of oral dosage form such as dizziness, nausea, weight loss, sleep problems, GI disorders, etc. Accordingly, increased safety leads to easier dose escalation in patients with severe symptoms. Patch offers various advantages compared to the existing oral formulation in terminal diseases currently humankind is fighting against. Pramipexole for Parkinson's Disease is one part of our R&D pipeline as a patch development similar to donepezil patch. We are currently in the pre-clinical stage of testing the pramipexole patch.

The market for transdermal drug delivery is dominated by big names such as Mylan, UCB, J&J and Novartis. What differentiates iCure?

The two important factors to consider when designing transdermal patches are skin flux and medical rationale. Skin flux is a measure of the diffusion of molecules through the skin barrier, i.e. skin permeability. While the medical rationale is fixed, available skin flux can be modified through various technological methods. We enlarge the skin permeability with our core technologies and eventually expanded TDDS drug candidates into the patch.

Donepezil patch is one example of the superiority of our technologies compared to those of other companies. Multiple companies, including the original developer of the drug, have failed to develop a donepezil transdermal patch with sufficient dermal flux. We are the only company to successfully bring such a patch to clinical Phase III that acts on the patient. The technology, research process and result, on the whole, illustrates that iCure has the capabilities for the global market.

What capabilities have you developed to manufacture transdermal patches for the global market?

Above all, we own an outstanding R&D program and researchers to develop patches in high demand worldwide. In addition to existing factories, we are currently building a new cGMP grade factory in Wanju, South Korea. We are establishing a strong team of qualified personnel qualified in QC/QA internally. The new factory is planned to acquire KGMP certification next month and we will also apply for cGMP certification this year. In order to prepare for cGMP certification, we have

scheduled several mock audit programs in upcoming months to assure the factory and product quality.

How do you plan to market your transdermal patches internationally?

The core competency towards the overseas expansion is the product itself. Surely, the marketing strategy and superior international partners are critical as well. In order to commercialize the patch internationally, we are continuously contacting and communicating with a few multinational pharmaceutical companies for partnering.

As I mentioned, iCure delivers OEM/ODM services while also developing its own products and brands in both the pharmaceutical and dermo-cosmetic markets. However, we do not simply license-out our technology, as our ambition is to become a global leader in the field of transdermal patches. Regarding branding for instance, we employed the global organization of naming and brand identity consultancy specialized in the pharmaceutical market. They have worked together with us to develop a global brand name for our donepezil patch: Donhesive.

How is iCure positioned to ride the wave of the surging cosmeceutical market in Asia?

There are strong synergies between the pharmaceutical and cosmeceutical markets in general, and especially for our transdermal technology. The need for organic and cosmeceutical products are significantly increasing. When we started utilizing our transdermal technology to develop hydrogel and sheet masks, I never expected cosmeceuticals to become so popular around the world. We are now providing ODM services to major global cosmetic companies with hydrogel facial masks and expanding to skincare products with patented cell-penetrating botulinum peptide. We are looking forward to providing these products, which made a big hit in Korea, to the global market in the upcoming years. In order to cater to the growing demand in China and other Asian countries, we are building a new cosmetic factory in addition to our already-existing facilities. Sooner or later, we will establish an affiliate in Los Angeles to penetrate the U.S. market as well.

Where would you like to see iCure in the next three to five years?

After our listing on the KOSDAQ last year, iCure has become a well-recognized company in Korea. In the next three to five years, our goal is to be a household name on the global stage. In other

words, we want iCure to be the first company that springs to mind when it comes to transdermal patches. Moreover, now that we hold a strong grasp on transdermal technology, we would like to diversify our business by developing an advanced oral dosage technology platform.

We have started working on oral forms of oxaliplatin and pemetrexed for metronomic cancer therapy that have shown a significant increase in efficacy compared to MTD therapy of oxaliplatin and pemetrexed injections. Additionally, by combining our oral formula with PD-1 checkpoint inhibitors, we have demonstrated a remarkable reduction in cancer cells compared to metronomic therapy and immunotherapy alone. These promising results make us hopeful for the future. Along with transdermal and oral drug delivery system, iCure will continue its growth globally with innovative drugs for enhanced patient care.

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