

## Allergan Closes Zeltiq Deal: Officially Adds Coolsculpting to Portfolio

It's a done deal—Allergan now owns Zeltiq Aesthetics. Allergan acquired Zeltiq for approximately \$2.4 billion in cash. Zeltiq stockholders approved the transaction during its stockholder meeting held on April 27. With the acquisition, Allergan adds Zeltiq's flagship CoolSculpting System to their portfolio.

## Non-Invasive Pigmented Lesion Assay Almost Doubles Biopsy Specificity

Dermatologists who incorporate DermTech's noninvasive pigmented lesion assay may biopsy fewer benign pigmented skin lesions and miss fewer melanomas, according to a new study in *JAMA Dermatology*.

DermTech's technology allows the analysis of skin biopsy samples collected non-invasively using an adhesive. In this study, 45 dermatologists evaluated 60 clinical and dermoscopic images of clinically atypical pigmented lesions, and the pigmented lesion assay improved biopsy specificity from 32.1 percent to 56.9 percent, and increased biopsy sensitivity by 4 percent, the study showed. (For more on this study, read *Oncology Watch* on page 53.)

## Forging Ahead For Clear-Cut Best Practices for MOHS Surgery

New research on the average number of surgical slices made during Mohs micrographic surgery (MMS) will serve as a first step toward identifying best practices for MMS, as well as identifying and informing physicians who may need re-training because their practice patterns deviate far from their peers.

In an analysis of Medicare Part B claims data submitted by more than 2,300 US physicians from January 2012 to December 2014, the average number of cuts among all physicians was 1.74. The median was 1.69 and the range was 1.09 to 4.11 average cuts per case. Measuring a surgeon's average number of cuts was recently endorsed by the American College of Mohs Surgery (ACMS) as a clinical quality metric used to assess its members.

The new analysis, which was published in *JAMA Dermatology*, is part of a medical quality improvement

project called "Improving Wisely," funded by the Robert Wood Johnson Foundation and based at The Johns Hopkins University. The initiative focuses on developing and using individual physician-level measures to collect data and improve performance. The U.S. Centers for Medicare and Medicaid Services provided broad access to their records for the study.

Of the 2,305 physicians who performed MMS during each of the three years studied, 137 were considered extremely high outliers during at least one of those years. (An extremely high outlier was defined as having a personal average of greater than two standard deviations, or 2.41 cuts per case, above all physicians in the study.) Forty-nine physicians were persistently high outliers during all three years.

Physicians in solo practice were 2.35 times more likely to be a persistent high outlier than those in a group practice; 4.5 percent of solo practitioners were persistent high outliers compared to 2.1 percent of high outlier physicians who performed MMS in a group practice, the study showed. Volume of cases per year, practice experience and geographic location were not associated with being a high outlier.

Low extreme outliers, defined as having an average per case in the bottom 2.5 percent of the group distribution, also were identified. Of all physicians in the study, 92 were low outliers in at least one year and 20 were persistently low during all three years.

Potential explanations for high outliers include financial incentive as the current payment model for MMS pays physicians who do more cuts more money, the study authors note. These charges are ultimately passed on to Medicare Part B patients, who are expected to pay 20 percent of their healthcare bill. Low outliers may be explained by incorrect coding, overly aggressive initial cuts, or choice of tumors for which MMS is not necessary, they write.

The researchers also gathered the following data for each physician: sex, years in practice, whether the physician worked in a solo or group practice, whether the physician was a member of ACMS, whether the physician practiced at an Accreditation Council for Graduate Medical Education site for MMS, volume of MMS operations, and whether the physician practiced in an urban or rural setting. Physicians had to perform at least 10 MMS procedures each year to be included in the analysis.

Although the study was limited by lack of information about each patient's medical history, or the diameter or depth of each cut, it's a meaningful step toward identifying and mitigating physician outliers, the study authors conclude.

## RxPhoto Releases Updated HIPAA-Compliant Mobile Clinical Photography App

RxPhoto has released version 3 of its mobile medical photography solution for medical practices and providers.

Medical practices can now remain HIPAA compliant while using their mobile devices to securely capture, manage, and share medical photos and videos.

RxPhoto says it helps providers increase patient satisfaction and improve workflow through its patented HIPAA mobile and cloud-based patient photography platform. The RxPhoto medical app eliminates the need for expensive and cumbersome

# Take 5

WITH ANJA KRAMMER, BioPHARMX

*BioPharmX Corporation's topical minocycline gel for acne, BPX-01, achieved its primary endpoint in a phase 2b clinical trials reported this month (see p. 31). Practical Dermatology<sup>®</sup> recently spoke with BioPharmX President Anja Kramer about the company and its future.*



### 3. MINOCYCLINE IS AN ATTRACTIVE TARGET FOR DEVELOPMENT.

Among APIs, minocycline's "dual benefit" made it an obvious target, Ms. Kramer says. "When you think about the API minocycline, it not only has an antibacterial benefit but also has an anti-inflammatory benefit. When you think about acne patients, clearly those are both key factors."

### 1. BIOPHARMX IS FOCUSED ON DRUG DELIVERY.

The company looks at core competencies from the perspective of improved drug delivery to meet unmet medical needs, Ms. Kramer says. "The first delivery system that we've come out with was fully invented in-house...When you think about developing a topical delivery system you really need to be able to enhance the delivery of the drug, but the area that no one has been able to address well is penetration." Most companies focus on stabilization. "To do that most companies have worked with an oil-based environment. What it doesn't allow though, is for those molecules to then be fully solubilized...Our hydrophilic solution is able to maintain the stability, which is a difficult challenge, and it allows the active to fully solubilize. Those are the two good benefits."

### 4. THIS APPROACH DIFFERS FROM GENERICS.

Generics drugs are big business. So why isn't BioPharmX working in that space? "If I could solve the problem in a cost-effective manner that is comparable to something like generics, but do it with a breakthrough new product that gives the highest efficacy, that would be the ultimate win," Ms. Kramer says. "For me, setting out to accomplish that first and foremost made a lot more sense. We weren't creating NCEs...We did have to invent a whole new system as opposed to just taking a drug, like a generic house would do, and fully repurposing it through a generic brand."

### 2. THE API PROCESS OFFERS COST SAVINGS.

BioPharmX has spent less than \$40 million on its unique topical gel for acne. By focusing on delivery of an approved drug, the company has been able to reduce costs. This means a relatively low-cost innovation in the space of antibiotic therapy for acne—which hasn't seen a major development since the launch of topical erythromycin, Ms. Kramer says. "We say what if? What if we could take the best molecules that are currently solving the problem and get them into the skin?"

### 5. THERE'S MORE TO COME.

"We've got a good pipeline and that's off just the first delivery system," Ms. Kramer promises. BPX-01 is the first candidate off the topical delivery platform and could potentially be applied to any tetracycline class molecule. "Horizontally, we have initiated a tolerability and usability study for rosacea, that's an indication expansion. Then separately we are exploring right now other APIs off this delivery system. We haven't disclosed yet to what indications but we probably will in the next three to four months."

photography equipment with its secure and intuitive medical photography system. RxPhoto's web-based image and data management platform provides tools to not only store medical photos, but to use those photos to educate patients.

Since 2011, RxPhoto's mission has been to help providers measurably improve outcomes and increase patient satisfaction using secure mobile and cloud-based communication. Providers use RxPhoto's software, services and support to transform the way they use patient photos for visual documentation.

RxPhoto's medical app converts an iPhone or iPad into a clinical photography system that helps practices take standardized and consistent patient photos in which all photos are encrypted and pushed to the RxPhoto HIPAA compliant cloud. RxPhoto has not only improved their aesthetic photo capturing capabilities, they have also added digital consent forms and robust sharing and showcasing tools so that practices can use consented patient photos for record keeping, expectation management, marketing and illustrating services.

## Phase 4 Studies of Restylane Refyne and Defyne Show Lasting Natural Benefit

Two Phase 4 clinical studies of Restylane Refyne and Restylane Defyne show that the natural-looking results last. Specifically, the Natural Expression study found that natu-

ralness in facial expressions was at least maintained in 95 percent (60/63) of patients (primary objective). Additionally, results from the Dynamic Strain study found that 83 percent (25/30) of patients had enhanced attractiveness, looked younger and at least maintained naturalness, post Restylane Refyne and Defyne injections.

The findings were presented during the Galderma Symposium at the 15th Aesthetic & Anti-aging Medicine Annual World Congress (AMWC), which was held April 6-8 in Monaco. Restylane Refyne and Restylane Defyne were recently FDA-approved for the treatment of nasolabial folds in patients over the age of 21.

## Valeant's Patient Access and Pricing Committee Prices SILIQ as Lowest Costing Injectable Biologic for Psoriasis

Following the evaluation and approval of its Patient Access and Pricing Committee (PAPC), Valeant Pharmaceuticals International, Inc. has decided to list SILIQ (brodalumab) injection at \$3,500 per month, which is the lowest injectable biologic psoriasis treatment currently on the market. SILIQ will also be included in the company's patient access program to further offer financial support and access to patients ■

## Letter to the Editor

Congratulations and thank you for the outstanding photo art on the cover of the April 2017 issue of *Practical Dermatology*®. Your photo tells a story that is truly worth a thousand words.

Oftentimes, an article intended to promote skin cancer prevention is illustrated with an inappropriate image such as a bikini-clad model applying sunscreen while sunbathing at the beach. Your photograph of comfortable beach chairs covered by a sea of umbrellas sends the right message! I just wish that vacation resorts and ocean cruises would take a cue from you and update their policies to routinely offer and promote more sun-safe relaxation options as opposed to the typical row of chaise lounges intended to beckon clients to lay out and work on their tan.

At the National Council on Skin Cancer Prevention ([skincancerprevention.org/programs/dont-fry-day](http://skincancerprevention.org/programs/dont-fry-day)), our theme for this year's Don't Fry Day (May 26) is "Throw Shade on Tanning." Your journal cover does just that and I strongly applaud you for it.

Best regards,  
Jeff Ashley, MD  
Dermatology  
President, Sun Safety for Kids

