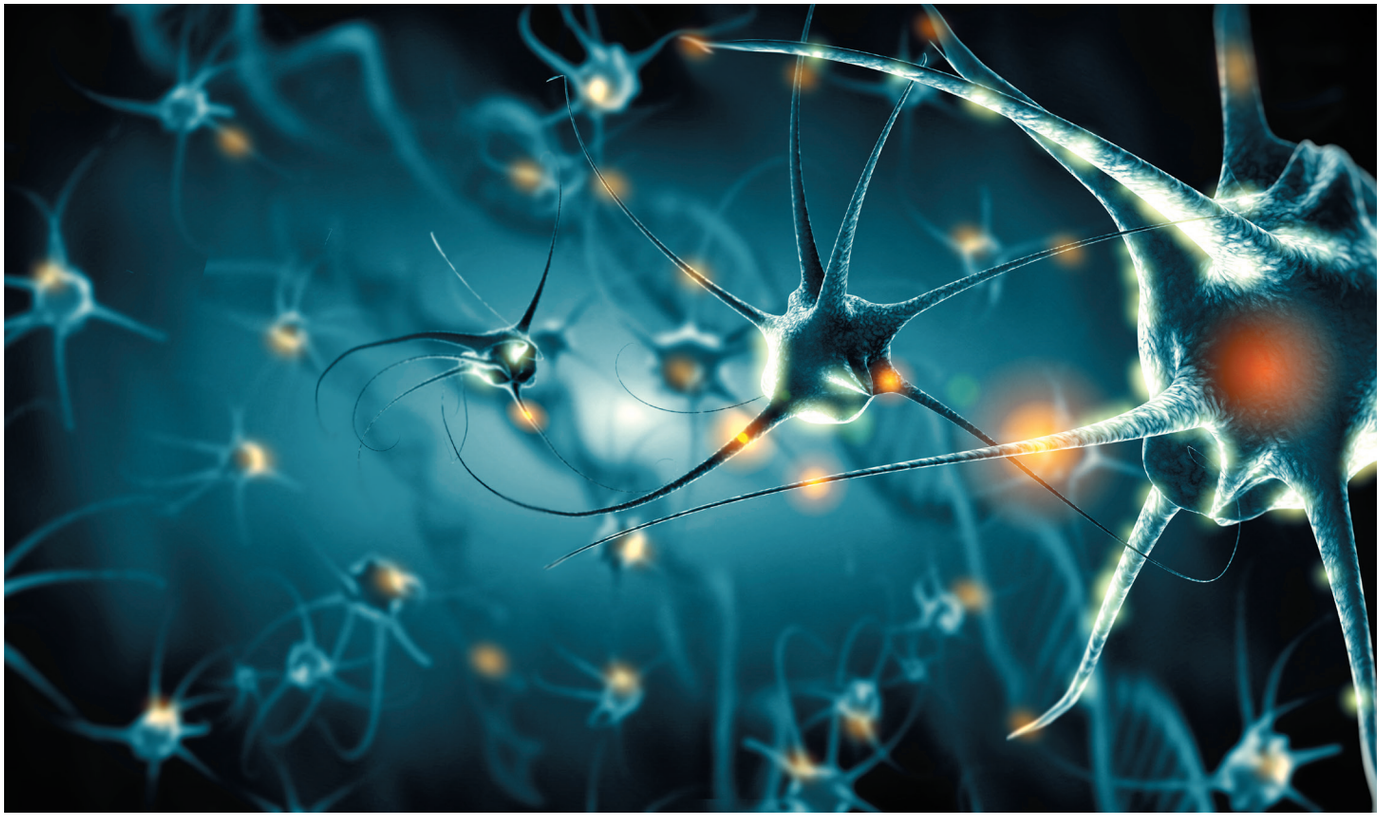

# HOW REVANCE'S RT002 IS POISED TO SHAKE UP THE AESTHETICS INDUSTRY

**Wendy Lewis** investigates the company's plans for seeking FDA approval of the first potentially long-acting neuromodulator

**ALTHOUGH THERE ARE SEVERAL neuromodulators around the world that have yet to enter the US market, there is a definite void noted among aesthetic injectors for something that performs in a new and unique way, in the US and abroad. A neuromodulator with a unique characteristic like longer lasting effects, would offer a distinct advantage to overcome the obstacle of patients who are hesitant to commit to quarterly visits because of time, money, or needle fatigue, and to encourage more patients to enter the market to get treated.**

Enter Revance® Therapeutics, Inc, a biotechnology company founded in 2002, whose mission has been to develop next-generation neuromodulators for use in treating aesthetic and therapeutic conditions. In December of 2018, Revance announced its long-acting neuromodulator, DaxibotulinumtoxinA for Injection (RT002), delivered positive results in treatment of glabellar (frown) lines in the SAKURA 3 Phase 3 open-label, long-term safety study. These results help pave the way for a Biologics License Application (BLA) in the first half of 2019, and a much-anticipated commercial launch in 2020.

According to Dan Browne, co-founder, President and CEO of Revance, 'It's all about innovation in science for us. It's the first and only botulinum toxin product formulated without any human-blood derived products and is not manufactured using any animal-derived proteins. We believe the combination of a highly purified botulinum drug substance, with the first and only stabilising excipient peptide, gives RT002 the long-lasting results in practice and creates an entirely new category of neuromodulators that has the potential to improve physician and patient experience with neuromodulator treatment.'

> "We believe the combination of a highly purified botulinum drug substance, with the first and only stabilising excipient peptide, gives RT002 the long-lasting results in practice and creates an entirely new category of neuromodulators that has the potential to improve physician and patient experience with neuromodulator treatment."
>
> ***Dan Browne***
> *Co-founder, President and CEO of Revance*

Browne continues, 'Despite recent studies by Revance's competitor's attempting longer duration by leveraging increased doses, no one has been able to show viability with the current products on the market. It is not simply a doubling of the dose as some have speculated. In clinical trials, RT002 delivered consistency, predictability and durability of results with a similar amount of core toxin seen in other products.' ▷

**WENDY LEWIS** is President of Wendy Lewis & Co Ltd, Global Aesthetics Consultancy, author of 12 books, including Aesthetic Clinic Marketing in the Digital Age (CRC Press), and Founder/ Editor-in-Chief of www.beautyinthebag.com.

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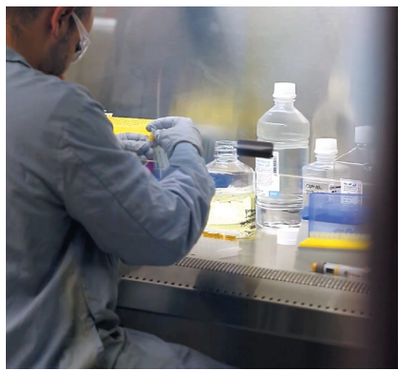
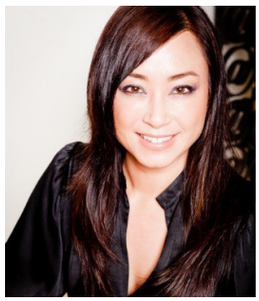



**Dan Browne**, Co-founder, President and CEO of Revance

**Sabrina Fabi**, MD, dermatologist and investigator, La Jolla, CA



**Jackie Yee,** MD, plastic surgeon, Miami, FL

**Shannon Humphrey**, MD, dermatologist and investigator, Vancouver, CA

▷ 'In addition, our current physician and consumer research clearly indicates that the market for neurotoxins is underpenetrated, currently at a range of only 10%. The number one request we see from both physicians and consumers, is for a long-lasting neuromodulator, which RT002 will be poised to address at launch,' says Mr. Browne.

## The neuromodulator market 2018

At the end of 2018, the US market had three neuromodulator players that have achieved FDA approval for cosmetic indications. The first was, of course, BOTOX® (Allergan, Inc.) in 2002, followed by Dysport® (Galderma) in 2009, and then by Xeomin® (Merz) in 2011. Evolus™ is developing a 900 kDa Botulinum toxin Type A complex, a potentially lower cost alternative and is anticipated to enter the market in 2019.

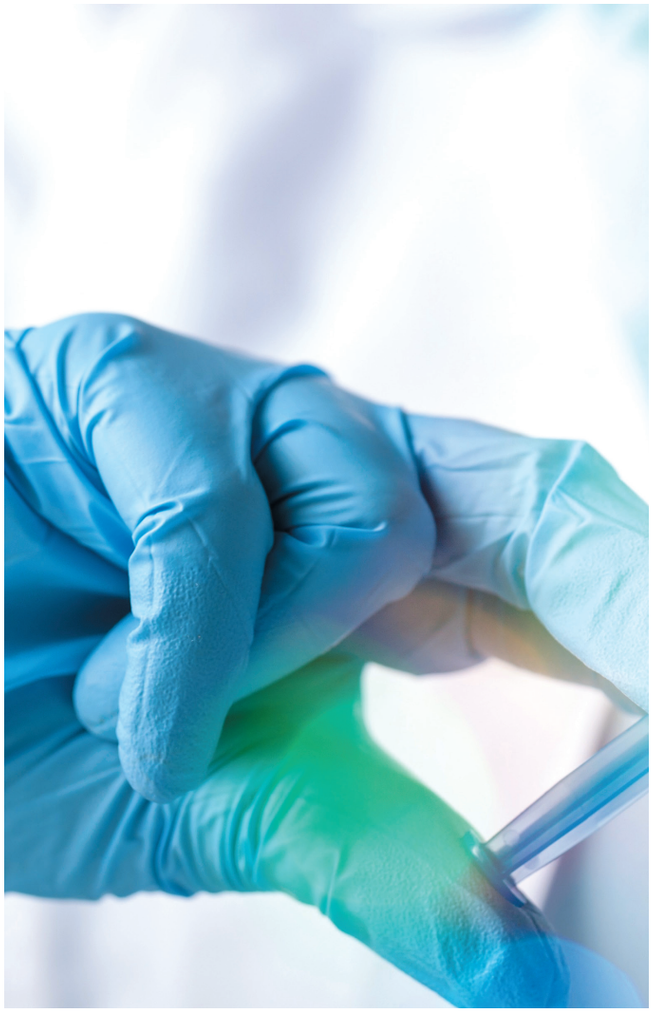
According to the IMCAS Tribune[1], among the top four market segments, injectable products comprising botulinum toxin and fillers is ranked as the largest segment in terms of value (42%), and the market is projected to grow by an average of 7.9% per year until 2021, from $4.4B to $6.0B.

RT002 is not just positioned as a glabellar line drug. It has versatility that Revance is exploring in the use and dosage of RT002 in the upper face, and an expansion into a broad range of neurological, musculoskeletal, and pain conditions. According to Browne, 'Our proprietary peptide technology was designed to create a pipeline of novel, differentiated therapies, that redefine the value of neuromodulator treatment and drives consumers and providers to demand performance and convenience that is achieved through twice a year neuromodulator treatment.'

Dermatologist and investigator, Sabrina Fabi, MD, a dermatologist in La Jolla, CA believes that RT002 may help grow aesthetic practices. 'Presently the longevity of results we can expect from neuromodulators as they are dosed and respectively priced is a limiting factor for some of my patients when deciding what aesthetic treatment to undergo. Just as we saw with fillers, when an HA filler was found to be safe and maintain a longevity of up to two years, and the cost wasn't doubled or tripled, patients found the cost benefit to be worth it. As a result, my filler practice grew. I anticipate that a longer lasting neuromodulator that is appropriately priced will finally make the perceived investment worth it for many patients who could benefit from the procedure and have held back,' she says.

> "Any patients that have been reluctant to enter the aesthetic space because neuromodulators only last three months may be more likely to get injected once they learn there is a longer-lasting alternative."
>
> ***Jackie Yee***
> *MD, plastic surgeon, Miami, FL*

Plastic surgeon Jackie Yee, MD, in Miami, FL was excited to learn about Revance's plans to introduce a neuromodulator that is longer lasting than those currently on the market. 'RT002 has some preliminary data that reveals longer duration up to six months compared to the available standard of three-four-month duration. It has the potential to give our patients a longer lasting benefit and to decrease the number of appointments per year from four visits to two visits, as the newest data released indicates.'



There are additional benefits for practitioners, cites Dr. Yee. 'For injectors, seeing patients for maintenance less often allows for more time in our schedules to see and treat new patients. In addition, any patients that have been reluctant to enter the aesthetic space because neuromodulators only last three months may be more likely to get injected once they learn there is a longer lasting alternative. Having a longer lasting neuromodulator is sure to be attractive and beneficial to any patients that are needle phobic or consider their injections uncomfortable,' she says.

Mr. Browne says, 'In the sheer evolution of healthcare, medications in all categories have gone from high frequency of use to a lower frequency of use, making them

more patient-friendly and doctor-friendly. This follows trends across industries to move to more convenient options, which many consider an upgrade in their treatment regimens. In addition, when products go from high to low frequency of usage, you not only see an increase in adherence and compliance, but the market itself will organically expand.

## Positive clinical data

In December 2017, Revance reported two Phase 3 clinical trials (SAKURA 1 and 2) that demonstrated RT002's ability to provide patients long-acting performance and duration of effect, with potentially just two treatments a year in both glabellar lines. In December 2018, the Phase 3 open-label, long-term safety study (SAKURA 3) was the final step in the SAKURA programme. The study enrolled nearly 2,700 patients across 66 reputable sites who received more than 3,800 treatments—up to three per patient—and were followed for more than 18 months. Overall, safety findings were consistent with the known profiles for currently available neuromodulators in aesthetics. Results confirmed that RT002 was generally well-tolerated, and no new tolerability or safety concerns were reported.

### TOP 4 AESTHETICS MARKET SEGMENTS (IMCAS TRIBUNE 2018)

**1** Botulinum Toxins, Dermal Fillers

**2** Active Cosmetics (Cosmeceuticals)

**3** Energy Based Devices, Lasers, Body Contouring Devices, Energy Based Women's Health Devices

**4** Breast Implants

According to investigator and dermatologist Shannon Humphrey in Vancouver, CA, 'The safety and efficacy data from SAKURA 1 and 2 were impressive, but now that we look at SAKURA 3, we've increased the numbers of participants and investigators and we continue to see really high levels of efficacy and favourable side-effect profiles. My personal observations around duration efficacy were consistent with the reported data.'

She continues, 'I think RT002 will have a place in my practice. I really see two areas that it might fit in. First, in terms of duration, it's a great opportunity to synchronise neuromodulator treatments with fillers and other treatments in my practice that we offer to patients twice a year. I also think there is a place to offer patients something that is truly differentiated, and I like to bring the best in terms of science for my patients.'

Based on investigator assessment, more than 95% of patients achieved a score of none or mild glabellar lines at maximum frown at week 4 after each of three treatments. Measuring duration of effect, the median time to return to baseline glabellar line severity was 28 weeks. Median time to loss of none or mild wrinkle severity was 24 weeks, with consistent results across age ranges, gender, and prior ▷

**Vince Bertucci,** MD,FRCPC, dermatologist and investigator, Toronto, CA

**W. Grant Stevens,** plastic surgeon, Marina Del Rey, CA and President of the American Society for Aesthetic Plastic Surgery (ASAPS)

**Steven Dayan,** MD, MD, plastic surgeon, Chicago, IL


▷ toxin user sub-groups. These results were also consistent with findings from SAKURA 1 and 2, positioning Revance to submit a BLA to the FDA, expected in the first half of 2019.

According to Toronto dermatologist and investigator Vince Bertucci, M.D., FRCPC, 'In my experience, market penetration for botulinum toxins has been somewhat limited by the fact that the aesthetic benefits last only three to four months. If approved, I believe that the longer duration of effect will prompt some of those individuals sitting on the sidelines to enter the market and avail themselves of treatment. Given the Phase 3 SAKURA data confirming a longer duration of effect, injectable treatments may be more convenient for patients, but will also allow physicians to schedule patients more efficiently,' he said.

> "Revance Therapeutics' long-awaited first product is well positioned to be a major addition for the aesthetics industry. That could be a gamechanger to grow the toxin market and attract new patients into doctors' offices."
>
> ***W. Grant Stevens***
> *Marina Del Rey, CA plastic surgeon, and President of the American Society for Aesthetic Plastic Surgery (ASAPS)*

Facial plastic surgeon Steven Dayan, MD anticipates RT002 to have early consumer interest. 'Word of mouth among consumers in aesthetics is very strong, especially in light of social media, the emerging power of influencers, and the growth of online communities like RealSelf®. One patient tells another patient who tells another patient about what's new and exciting. That kind of consumer buzz can be huge.'

## The future looks promising

'With the recent results of the Sakura 3 clinical trials, we are confident in RT002's ability to produce consistent and predictable results and anticipate that those results will be reflected in our upcoming and differentiated label, if approved by the FDA in 2020. We have high expectations RT002 will drive meaningful growth in the approximately $4 billion global neuromodulator market. This is a molecule that behaves and performs differently than the existing products and we have demonstrated a commitment to innovation without creating an adverse safety profile,' according to Mr. Browne.

Next, we are preparing for a 2019 Biologics License Application (BLA) submission for RT002 for the treatment of glabellar lines, while increasing our pre-commercial initiatives focused on understanding and breaking through the barriers to neuromodulator use that have stymied growth in the market,' he said.

Upon US FDA approval, Revance's goal is to launch their first product in 2020.

▶ ***Find out more at:*** *REVANCE.COM*

## References

1. IMCAS Tribune Press Release, February 2018

2. SAKURA 3 results presentation. Revance, December 2018. Available at: https://investors.revance.com/static-files/44313e27-b5bf-46d1-a33d-7b06902860e3 [Accessed December 23 2018]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