

Allergan to Acquire earFold(TM), an Innovative Medical Device for the Correction of Prominent Ears

Dublin And Marlow, England (ots/PRNewswire) -

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- Complements Allergan's leadership position in Medical Aesthetics and enhances

offering to Plastic Surgeons

- earFold(TM), for the correction of prominent ears and/or ear asymmetry in people aged

7 years and older,[1] was recently granted a CE mark for commercialisation in Europe

- A minimally-invasive treatment option[1] for those affected by the social stigmas

associated with protruding ears but are reluctant to undergo conventional otoplasty

surgery

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Allergan plc , a leading global pharmaceutical and aesthetics company, today announced that it has entered into an agreement under which Allergan will acquire Northwood Medical Innovation Ltd, developer of innovative implant technology, earFold(TM). earFold(TM) is an innovative medical device for the correction of prominent ears, with or without asymmetry, in patients aged 7 years and older. earFold(TM) received a CE mark in April 2015, and has been made available by Northwood Medical Innovation Ltd to trained and accredited plastic surgeons, otolaryngologists (Ear, Nose and Throat) and maxillo-facial surgeons, primarily in the UK. Upon closure of the deal with Northwood Medical Innovation Ltd, Allergan intends to commercialise the product widely across Europe, in line with its CE mark, and will continue to explore the regulatory pathways and necessary clinical data requirements to commercialise this medical device in other countries, including the United States of America.

Prominent or protruding ears are thought to affect approximately 1-2 percent of the population, which is about 100 million people worldwide[2],[3]. While there is no universally agreed definition for prominent ears, there is general agreement that ears appear increasingly prominent when the outer rim of the ear protrudes away

from the side of the head by more than 20mm[1]. This can have a considerable psychological impact on a person's life; insecurities about their appearance, teasing or bullying can lead to a loss of confidence and psychological distress[2]. The current treatment options are limited with the most conventional being surgery, called otoplasty or pinnaplasty. The risks associated with these procedures include adverse reactions to general anaesthetic, infection, the development of keloid scarring and sometimes the need for re-do operations (due to asymmetric outcomes or relapse)[4]. As a result of these risks, patients may choose to remain untreated. Nevertheless according to the International Society of Aesthetic Plastic Surgery (ISAPS), approximately 247,518 ear surgery operations took place across the world in 2014, making it one of the most common cosmetic procedures performed [5].

"Allergan is constantly searching to partner with or acquire companies with disruptive technologies that offer substantive value to our customers, often opening up new categories or setting new trends within our specialist segments. An example of this is the strategic acquisition of KYTHERA, with KYBELLA(R) (marketed as BELKYRA(TM) in Canada) (deoxycholic acid) injection, the only FDA approved non-surgical pharmaceutical treatment for reduction of submental fat, or double chins," said Paul Navarre, President and EVP of International Brands at Allergan. "earFold(TM) technology adds another innovative product to our medical aesthetics product portfolio, especially for the plastic surgeons we serve today, and has the potential to expand the number of patients interested in corrective surgery as it provides an alternative treatment that may appeal to those who have been reluctant to undergo traditional surgical procedures. Many of Allergan's plastic surgery customers currently perform otoplasty procedures, emphasizing our commitment to serving the unmet needs and practice of plastic surgery."

earFold(TM) is a small implantable medical device made from a short strip of nitinol metal alloy, which is specifically designed to retain a preset shape. Following injection of a local anaesthetic, it is carefully inserted under the skin using an introducer, and works by gripping the cartilage of the ear, enhancing or creating the shape of the anti-helical fold - thereby reducing the prominence of the ear. Including the initial consultation, the procedure takes about 15-20 minutes to complete and can be performed within an outpatient setting, reducing the risk associated with a general anaesthetic. Given the preset nature of the nitinol strip, treatment with

earFold(TM) can deliver a consistently effective outcome. By contrast, otoplasty or pinnaplasty is a complex surgical procedure that requires a visit to a fully-fitted operating suite, requires a general anesthetic and is associated with significant down-time post treatment. The results from otoplasty surgery can be more difficult to predict in advance of surgery as the adjustments to the ear's shape can only happen during the procedure itself and are therefore left to the surgeon to control.

earFold(TM) has been studied in more than 400 patients with real world experience showing the benefit of providing patients with a rapid and predictable alternative to existing otoplasty techniques. On average, patients obtained a 34 percent reduction in the helical-mastoid (HM) distance (the distance measured from the outer rim of the ear to the side of the head)[6]. This reduction in prominence is similar to the results expected from standard otoplasty procedures[7]. Complication rates in the study were low (8 percent) and the main side-effects were pain, swelling and bruising of the ears[6].

"Following a complex outcome after a standard otoplasty procedure, early in my career, I was motivated to develop an alternative approach to correcting prominent ears," says Norbert Kang, Consultant Plastic Surgeon and creator of the earFold(TM). "In my clinical practice, there are a significant number of patients who are reluctant to undergo surgery and so put up with accepting the social hindrance of prominent ears. The beauty of the earFold(TM) treatment system is that it offers an evidenced-based alternative to standard otoplasty surgery that may meet the needs of a wider range of patients, by delivering immediate and predictable results, without the risks associated with general anaesthetic."

On completion of this deal, Allergan will establish a standardised training programme for surgeons on the earFold(TM) treatment system, in order to bring this valuable treatment option to more patients and ensure effective and safe outcomes.

NOTES TO THE EDITOR

The earFold(TM) Implant and Procedure

earFold(TM) is indicated for use in patients aged 7 years and older who have ear prominence (defined as a helical-mastoid distance of

greater than or equal to 20 mm) and/or significant asymmetry (defined as a difference in helical-mastoid distance of greater than or equal to 3 mm comparing left and right ears)[1]. The device can be used in conjunction with other operative procedures (e.g. cartilage scoring, conchal reduction or concho-mastoid sutures) for correction of prominent ears.

earFold(TM) is an implant made of a short strip of nitinol metal alloy, which is specifically designed to retain a preset shape. Nitinol alloy is widely used in medicine and is the same material that is used for coronary artery stents (for patients with heart disease due to a blockage of their arteries). The implant consists of a curved, wafer-thin strip of metal (approximately the same thickness as a human hair) which is plated with 24-carat gold to reduce the visibility of the implant under the skin. earFold(TM) implants reshape the ears with a simple procedure lasting just a few minutes.[1]

About Northwood Medical Innovation Ltd

Northwood Medical Innovation Ltd (NMI) was incorporated in 2010 to provide a vehicle for investment in the earFold(TM) concept. NMI is a privately held company based in London and was founded by the inventor of earFold(TM) - Dr Norbert V Kang - a Plastic Surgeon working at the Royal Free Hospital in London.

Marie-Claire Haines has been the Managing Director of the company since 2010. During this time NMI has successfully managed the early prototyping and development of the earFold(TM) concept, taking the technology through cadaveric and finally human clinical trials. The earFold(TM) implant has been commercialised in the UK since 2013, and was recently awarded a CE mark in April 2015, enabling NMI to start expanding sales in Europe and other countries.

About Allergan

Allergan plc , headquartered in Dublin, Ireland, is a unique, global pharmaceutical company and a leader in a new industry model - Growth Pharma. Allergan is focused on developing, manufacturing and commercialising innovative branded pharmaceuticals, high-quality generic and over-the-counter medicines and biologic products for patients around the world.

Allergan markets a portfolio of high quality products that provide valuable treatments for the central nervous system, eye care, medical aesthetics, gastroenterology, women's health, urology, cardiovascular and anti-infective therapeutic categories, and operates the world's third-largest global generics business, providing patients around the globe with increased access to affordable, high-quality medicines. Allergan is an industry leader in research and development, with one of the broadest development pipelines in the pharmaceutical industry and a leading position in the submission of generic product applications globally.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives.

Allergan Forward-Looking Statement

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 (such periodic public filings having been filed under the "Actavis plc" name). Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

References

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6) Allergan data on file 0077

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Rückfragehinweis:

Janet Kettels +44-7738-506-476

Karen Dennehy +44-7824-017-950

Lisa DeFrancesco

Investor Relations +1-862-261-7152

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