

May 3, 2019

To,  
Dy. General Manager  
Department of Corporate Services,  
BSE Ltd.,  
P. J. Towers, Dalal Street,  
Fort, Mumbai – 400 001.

To,  
The Manager – Listing,  
The National Stock Exchange of India Ltd.,  
Plot No. C/1, G Block,  
Bandra Kurla Complex,  
Bandra (E), Mumbai – 400 051.

Ref: Scrip Code: 532296

Ref: Scrip Name: GLENMARK

**Sub: Glenmark Therapeutics Expands Specialty Portfolio with OTIPRIO® Co-Promotion Agreement in the U.S. with Otonomy for Acute Otitis Externa Indication**

Dear Sir,

With reference to the subject mentioned above, kindly find attached media release which is self explanatory.

Request you to kindly take the same on record.

Thanking you,

Yours faithfully,  
**For Glenmark Pharmaceuticals Limited**

**Harish Kuber**  
**Company Secretary & Compliance Officer**

**Encl:** as above

Press Release – For Immediate Release

## Glenmark Therapeutics Expands Specialty Portfolio with OTIPRIO® Co-Promotion Agreement in the U.S. with Otonomy for Acute Otitis Externa Indication

**Mumbai, India; May 3, 2019:** Glenmark Therapeutics Inc., USA, a wholly-owned subsidiary of Glenmark Holding SA., today announced a co-promotion agreement with Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology. Glenmark Therapeutics is dedicated to developing and commercializing a franchise of branded products for Glenmark Pharmaceuticals and is focused in the areas of respiratory and dermatology. Ryaltris™ (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg]), formerly GSP 301 Nasal Spray, is the company's leading respiratory pipeline asset and currently under review with the U.S. Food and Drug Administration (FDA) as a treatment of seasonal allergic rhinitis in patients 12 years and older. "Ryaltris" has been conditionally accepted by the FDA as the brand name.

This agreement provides Glenmark Therapeutics with an exclusive right to promote OTIPRIO (ciprofloxacin otic suspension) for the treatment of acute otitis externa (AOE) in patients 6 months of age and older due to *Pseudomonas aeruginosa* and *Staphylococcus aureus* in ear, nose and throat specialist offices in the United States and its territories. Financial terms for the multi-year agreement were not disclosed; however, Glenmark Therapeutics will provide Otonomy an annual co-promotion fee and provide reimbursement of a proportion of product support expenses. In addition, Otonomy will retain a share of the adjusted gross profits from the sale of OTIPRIO to Glenmark's accounts. Commercial rights for use of OTIPRIO in other indications, including treatment of bilateral otitis media with effusion in patients 6 months and older who need ear tubes, will remain with Otonomy.

*"We are pleased to collaborate with Otonomy on this agreement which represents an excellent opportunity to fit within our respiratory franchise and supports our strategy of maintaining commercial emphasis on specialists," said Robert Matsuk, President North America for Glenmark Therapeutics. "With FDA review of our first New Drug Application for Ryaltris well underway, we remain focused on developing new partnerships that bolster our specialty portfolio and commercial footprint in the U.S. This agreement is a clear example of Glenmark Therapeutics' efforts to maximize and grow our presence by pursuing opportunities both through external partnerships and our internal R&D pipeline."*

### About Glenmark Therapeutics' Respiratory Pipeline

Glenmark's respiratory pipeline is specifically aimed at addressing the global public health burden of allergic rhinitis, asthma and chronic obstructive pulmonary disease (COPD), and includes investigational treatments across the disease spectrum. This includes Ryaltris (GSP 301 Nasal Spray), an investigational combination antihistamine plus steroid nasal spray for the treatment of seasonal allergic rhinitis currently under review by the FDA. It also includes GBR 310 (omalizumab), a proposed biosimilar candidate intended for the treatment of allergic asthma and chronic idiopathic urticaria; and GSP 304, which is being investigated for the treatment of COPD.

### About Glenmark Therapeutics

Glenmark Therapeutics Inc., USA is a wholly-owned subsidiary of Glenmark Holding SA. The company is dedicated to building a franchise of branded products for Glenmark Pharmaceuticals, a global, integrated pharmaceutical company with operations in more than 80 countries. Glenmark Therapeutics will initially focus its efforts on launching and commercializing assets in the therapeutic areas of dermatology and respiratory. Glenmark Therapeutics has a short- and long-term pipeline of investigational medicines intended to meet the needs of patients suffering from a variety of dermatological and respiratory conditions and is consistently working to expand its product portfolio.

### About Otonomy

Otonomy is a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology. The company pioneered the application of drug delivery technology to the ear in order to develop products that achieve sustained drug exposure from a single local administration. This approach is covered by a broad patent estate and is being utilized to develop a pipeline of products addressing important unmet medical needs, including Ménière's disease, hearing loss, and tinnitus. For additional information please visit [www.otonomy.com](http://www.otonomy.com).

### About OTIPRIO

OTIPRIO is a sterile, preservative-free, otic suspension of 6% ciprofloxacin administered as a single-dose by a healthcare professional. The thermosensitive suspension exists as a liquid at or below room temperature and gels when warmed.

For bilateral otitis media with effusion, OTIPRIO is administered during ear tube surgery as a single 0.1 mL (6 mg) intratympanic administration into each affected ear, following suctioning of the middle ear effusion. In two Phase 3 trials, a single intraoperative administration of OTIPRIO demonstrated a statistically significant reduction in the cumulative proportion of study treatment failures compared to tubes alone (p-value < 0.001).

For AOE, OTIPRIO is administered as a single 0.2 mL (12 mg) administration to the external ear canal of each affected ear. In a single Phase 3 trial, OTIPRIO demonstrated statistically significant clinical response defined as the complete absence of signs and symptoms of AOE (i.e., tenderness, erythema, edema, and otorrhea) compared to sham (p-value < 0.001).

### Approved Indications for OTIPRIO

OTIPRIO (ciprofloxacin otic suspension) is a fluoroquinolone antibacterial indicated for

- The treatment of pediatric patients 6 months of age and older with bilateral otitis media with effusion undergoing tympanostomy tube placement and
- The treatment of acute otitis externa in patients 6 months of age and older due to *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

### Important Safety Information for OTIPRIO

**Contraindications:** OTIPRIO is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, to other quinolones, or to any of the components of OTIPRIO.

**Warnings and Precautions - Potential for Microbial Overgrowth:** OTIPRIO may result in overgrowth of nonsusceptible bacteria and fungi. If such infections occur, institute alternative therapy.

**Adverse Reactions - Bilateral otitis media with effusion clinical trials:** Adverse reactions (incidence at least 3%) with OTIPRIO vs sham were: nasopharyngitis (5% vs 4%), irritability (5% vs 3%), and rhinorrhea (3% vs 2%). **Acute otitis externa clinical trial:** Adverse reactions (incidence at least 2%) with OTIPRIO vs sham were: ear pruritus (2% vs 2%), headache (2% vs 1%), otitis media (2% vs 1%), and ear discomfort (2% vs 0%).

**Use in Specific Populations - Pediatric Use:** The safety and effectiveness of OTIPRIO in infants below six months of age have not been established for the treatment of pediatric patients with bilateral otitis media with effusion undergoing tympanostomy tube placement and acute otitis externa.

Full prescribing information can be found at [www.OTIPRIO.com](http://www.OTIPRIO.com).

For further information, please contact:

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