

## **Job Description**

### **Country Medical Director**

#### **Company Background**

Amicus Therapeutics (NASDAQ:FOLD) is a biopharmaceutical company at the forefront of therapies for rare and orphan diseases. The Company has a robust pipeline of novel, first-in-class treatments in development for a broad range of human genetic diseases, with a focus on delivering new benefits to individuals with lysosomal storage diseases.

Amicus is building a leading biopharmaceutical company in the rare diseases, and is currently in the pre-commercial stage. In 2015 the Company plans to submit marketing applications in the US and EU for the oral pharmacological chaperone migalastat as a monotherapy for Fabry patients. This is a personalized medicine approach in which patients with “amenable mutations” respond to migalastat based on their genetics. Positive Phase 3 data have shown that treatment with migalastat has resulted in reductions in disease substrate, stability of kidney function and improvement in a key cardiac parameter (left ventricular mass index, or LVMI) in patients with amenable mutations.

For all other Fabry patients who do not have amenable mutations, Amicus is advancing migalastat in combination with enzyme replacement therapy (ERT). In 2015 Amicus plans to initiate a Phase 2 combination study as the next step towards establishing a Fabry franchise where all patients will take some form of migalastat to treat their Fabry disease

The Company is also leveraging its biologics platform technologies to develop bio-better ERT products. Its lead biologics program is a uniquely-engineered, bio-better Pompe ERT. Amicus is also applying its Chaperone-Advanced Replacement Therapy (CHART™) platform to combine ATB200 with a pharmacological chaperone to stabilize protein in blood and potentially improve ERT tolerability. A Phase 1/2 clinical study of ATB200 in combination with a pharmacological chaperone is expected to begin in the second half of 2015. Using the biologics and CHART technologies, Amicus is also developing next generation treatments for Fabry and MPS 1 with the potential to expand its pipeline into other lysosomal storage diseases.

As such Amicus now wishes to appoint a Country Medical Director that will work with the regional management team and the international medical team.

#### **Major Activities and Responsibilities**

- The role will be responsible for all aspects of Medical Affairs including medical support of product launches, leadership of country led studies, KOL mapping and contact, KOL relationship development and will work closely with Commercial, Regulatory, Pharmacovigilance colleagues and other support service teams e.g., Market Access, Medical Information, Publications. Management of RA, PV and Medical Information is not within the scope of this role.
- Further to team leadership and strategy management, key roles include risk management, scientific input to recalls / alerts, KOL development and Amicus brand building via customer meetings and presentations, colleague training, marketing support and promotional compliance activities as required.
- To define the Critical Success Factors and Key Performance Indicators for the country team consulting with the International medical team and business colleagues as appropriate.

- Provides leadership, development and management of the Field Medical Team (if applicable) working together to support the Commercial teams. Recruit, train and develop team members; identify and manage talent, enabling team to fulfil their potential. To coach and support individuals within the team in areas of relevant existing expertise and/or developing responsibility.
- Ensure that all the activities of the team are carried out in a fully compliant manner in accordance with Amicus policies and country laws and regulations.
- Manage the Medical Affairs budget at a country level
- Work alongside the Senior Management Team and other colleagues and commercial teams, undertaking any other duties commensurate with the level of responsibility outlined above, as and when required.

The new incumbent will be expected to drive the following key specific areas through his/her own activity:

- Raising the Disease Awareness and knowledge amongst all healthcare professionals of the relevant therapeutic areas and other decision makers in the relevant HC system via appropriate and well-targeted educational programs
- Support early suitable Patient Identification e.g. via appropriate local studies programs
- Collaborate with HCP and Key Thought Leaders (KTLs) in order to gain further insight regarding the appropriate cohort(s) of patients and adequate screening/diagnostic procedures to improve on otherwise misdiagnosed or undiagnosed patients
- Influence KOLs and associations towards the development or refinement of diagnostic algorithm(s) and/or management guideline(s) for Fabry Disease for their specialty(ies)
- Build a key opinion leader community around Fabry disease to strengthen disease awareness and to support the scientific development in the disease area, the regulatory and reimbursement efforts
- Supporting the development of a market entry plan for Galafold and future products (regulatory, patients advocacy, pharmacovigilance, KOL management, pricing & reimbursement)
- Supporting the reimbursement negotiations with local authorities and liaising with health authorities and payers as required
- Maintenance of up-to-date skills and knowledge regarding scientific medical best practice
- Contribute at local national and international medical conferences and symposia

### **Reporting Line**

This senior, pivotal and highly visible position within Amicus will report into both the Regional Vice President (RVP) and Head of International Medical Affairs in a dual reporting manner.

With responsibility for the Country medical function, the new incumbent will also take part actively in the Amicus International Medical Team and will therefore work closely with the other Medical Directors of Amicus major markets.

## **Qualifications and Background Requirements**

### **Educational Requirements**

- Medical degree or equivalent

### **Personal Qualities**

- Strong interpersonal skills. ( Communicative, persuasive)
- Team player. (Collaborative)
- Takes responsibility. (Ownership)
- Projects confidence and integrity. (Presence)
- Works well in ambiguous and challenging environments. (Resilient and Resourceful)
- Respectful of cultural differences. (Empathetic)
- Strategic outlook with tactical capability. (Vision/task balance)
- A passion for helping patients with rare diseases

### **Professional work Experience**

- Demonstrated initiative and an ability to build a market for a new therapy and an Medical organization from inception in the relevant country
- Substantial experience with a leading international life science company within the biopharmaceutical/pharmaceutical industry
- Strong understanding of the respective country's Health Care system including health technology assessment, regulatory processes and pharmacovigilance requirements
- Thorough experience and confidence when positioning biologic products with selected KOLs and prescribing physicians and hospitals
- Experience in communicating and building relations with authorities, health care sector professionals including specialist care and sales, as well as KOL management
- Strong in delivering well defined measurable results (plan vs. actual)
- International awareness and orientation with very good business acumen

### **Compensation**

- A competitive compensation package will be presented to the right individual including base salary, bonus, equity and healthcare.

### **Location**

- Based in the respective Country Headquarters office
- Domestic and International travel required

Overall, this position reflects an excellent opportunity for an experienced senior Medical Affairs leader, who is ready for a new, exciting challenge to build a function from scratch and establish a new medical community in an area of high medical need.