

Overview

Advanced Life Sciences is a biopharmaceutical company engaged in the discovery, development and commercialization of drugs in the areas of infection, oncology and respiratory disease. The Company's lead product candidate, Restanza, is a novel once-a-day oral antibiotic developed for the treatment of respiratory tract infections.

OTC BB: ADLS
Market Cap: \$9.45M at 07-30-10
52 Week Range: \$0.034 - \$0.68
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Advanced Life Sciences has assembled a promising pipeline of clinical and preclinical candidates using its internal discovery platform of medicinal chemistry and structural biology, coupled with in-licensing promising new products. The Company has three product candidates that are either in clinical development or approved to begin clinical development.

Restanza™ Pipeline

| Community Acquired Bacterial Pneumonia | | Discovery | Preclinical | Clinical | FDA Review | Commercialization |
|--|--|----------------------|--------------|----------|------------|-------------------|
| Oral - Adults | | [Progress bar: ~90%] | | | | |
| Oral - Pediatric | | [Progress bar: ~60%] | | | | |
| IV - Adults | | [Progress bar: ~60%] | | | | |
| Biodefense | | In Vitro | Small Animal | Primate | FDA Review | Stockpile |
| Anthrax | | [Progress bar: ~90%] | | | | |
| Plague | | [Progress bar: ~90%] | | | | |
| Tularemia | | [Progress bar: ~90%] | | | | |
| Melioidosis | | [Progress bar: ~30%] | | | | |

Restanza™ Program

With increasing worldwide resistance rates to current macrolide and penicillin antibiotics there is a growing medical need for new antibiotics. Restanza was created to address this need and is being developed for the treatment of community-acquired bacterial pneumonia (CABP). Restanza has exhibited high potency against key susceptible and resistant pathogens, including macrolide, penicillin and fluoroquinolone resistant *Streptococcus pneumoniae*. Restanza also exhibits strong activity against community-acquired *Methicillin-Resistant Staphylococcus Aureus* (CA-MRSA).

In addition to its potential utility in CABP, Restanza has shown effectiveness against pathogens that represent Global Public Health And Bioterror threats. It is being developed to treat airborne bacterial bioterror agents such as anthrax, plague, tularemia and melioidosis. As resistance to the first-line treatments grows, there is a medical need for new therapeutics that work differently than existing agents to treat anthrax infection, and the United States Food and Drug Administration (FDA) has granted Orphan Drug Designation to Restanza for the prophylactic treatment of anthrax, plague and tularemia.

About Community Acquired Bacterial Pneumonia

CABP is defined as a lower respiratory tract infection caused by pathogens such as *Streptococcus pneumoniae* and *Haemophilus influenzae* that is not acquired in a hospital or long term care facility. Resistance rates to these key pathogens are reaching alarming levels. When the infection is acquired, the lungs' air sacs fill with liquid, making it difficult for oxygen to penetrate through the lungs. If CABP is not treated properly, it can result in death, especially to people with weakened immune systems, such as the elderly. Macrolides and penicillins are currently the first-line treatments for respiratory tract infections such as CABP.

- The sixth leading cause of death in the US
- An estimated 5.6 million cases of CABP occur annually in the US, resulting in approximately 10 million physician visits and 1.1 million hospitalizations
- The estimated total annual cost of healthcare for CABP in the US is \$8.4 billion, with prescribed antibiotics accounting for \$2 billion annually
- The cost of hospitalized CABP patients unresponsive to penicillins or macrolides is \$15,000 per patient versus \$200 office visit with effective prescription
- The cost of collateral damage in the form of *Clostridium difficile* associated disease (CDAD) is \$1 billion in the US and growing

Recently Accomplished Milestones

September 2008

NDA successfully filed (eCTD)

- NDA database: ~5200 subjects, 53 clinical studies, full preclinical, toxicology and manufacturing data package
- Successful Phase III program demonstrated non-inferiority to standard of care and favorable safety profile

June 2009

FDA AIDAC meeting conducted

- Positive vote on safety
- Negative vote on efficacy
- In light of new FDA CABP guidance, panelists sought more efficacy data

July 2009

FDA Complete Response Letter received

- Additional clinical data required to demonstrate efficacy
- No GCP violations or safety issues raised

July 2010

Submitted Final Special Protocol Assessment for Restanza in CABP to FDA

Management Team

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