New Frontiers in COPD: What’s Next on the Treatment Horizon?

Aruni S. Arachchige Don, Ph.D.
Senior Consultant, Defined Health

Robert Vender, M.D., F.A.C.P.
Professor of Medicine,
Division of Pulmonary, Allergy, and Critical Care Medicine, Penn State Milton S. Hershey Medical Center

Irfan Rahman, Ph.D.
Professor of Environmental Medicine (Pulmonary), and Public Health Sciences, Department of Environmental Medicine, University of Rochester Medical Center

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Defined Health is Pleased to Present:

29TH Annual Cancer Progress Conference  
May 8-9, 2018  
www.cancerprogressbyDH.com

BioEurope Spring 2018  
March 12 – 14, 2018  
Amsterdam, The Netherlands  
www.therapeuticinsight.com

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ASH Annual Meeting | December 9 - 12, 2017, Atlanta, GA | http://www.hematology.org/Annual-Meeting/
COPD is a Complex Disease with an Increasing Prevalence; Expected to Become a Major Global Burden in the Near Future

- Chronic obstructive pulmonary disease (COPD) is a complex, chronic lung disease that occurs in a heterogeneous patient population characterized by airway obstruction, shortness of breath, cough, phlegm and chronic persistent inflammation of lung tissue.

  - 65M people worldwide according to the WHO
  - 6.3% of adults or an estimated 15M adults in the US with physician diagnosed COPD
  - Prevalence increase with age (>11.6% in those ≥65 yrs)
  - Increase in prevalence expected over the next decade

Hospitalizations Due to COPD Exacerbations are Key Driver Associated with Significant Healthcare Costs

- $50B dollars spent on COPD treatment compared to $125B for costs of cancer care (estimates in the US in 2010)
- Nearly 2/3 of the total COPD expenditures are for direct costs; hospitalization for COPD exacerbations is the biggest cost driver
- Total healthcare costs increase with disease severity, with advanced severe disease patients having the greatest impact on overall costs
- High patient burden (monthly out-of-pocket costs/co-pays for COPD medication AND poor quality of life associated with disease)

Smoking is the Number #1 Risk Factor for COPD, but Not All Patients Who Smoke Develop This Condition

♦ COPD represent a spectrum of manifestations and this diversity in individual presentation makes COPD quite challenging to manage

♦ It is estimated that ~25% of COPD patients in the US have never smoked. Persistent low-grade pulmonary and systemic inflammation are present in COPD, independent of cigarette smoking

- 10-20% of COPD cases in the US is caused by exposure to inhaled particles other than cigarette smoke: occupational or chemical exposure (vapors, irritants and fumes) found in indoor and outdoor air pollution

Identification of Biomarkers and Characterization of Phenotypes is an Active Area of Research in COPD

- Genome wide association studies and whole-exome sequencing suggest the presence of susceptibility and resistance genes as well as epigenetic events that modify gene function.
- Large observational studies (ECLIPSE, SPIROMICS, COPDGene) highlight efforts being made to stratify and study patient subsets. The goal is to cluster COPD patients into groups and identify potential biomarkers. Despite these efforts, results have fallen short in clinical practice due to tremendous variability in terms of the clinical presentation and the impact of their disease on their overall health (e.g., presence or absence of co-morbidities, etc.)

Source: American Journal of Respiratory and Critical Care Medicine Vol. 196 No. 4 (2017); Nature Reviews Disease Primers 1, Article number: 15076 (2015); 5. EMBO Molecular Medicine (2012) 4, 1144-1155
COPD is a Systemic Disease Analogous to Other End Stage Diseases

- Evidence suggests a link between COPD and many other end-stage conditions, for example, cardiovascular disease (CVD), peripheral artery disease (PAD), etc.

- For many COPD patients, common co-morbidities have a much greater impact on the patient’s overall health
  - COPD patients are at increased risk for CVD, and most deaths in COPD are attributed to CVD

- Inflammation, narrowing of blood vessels and fibrosis are common features in many of these end-stage conditions

Disease Severity Classification of GOLD I-IV Used for Decades to Guide Treatment Decisions Has Recently Been Updated to GOLD A-D

**Chronic Obstructive Pulmonary Disease (COPD)**

- **GOLD I**: Mild, $\text{FEV}_1 \geq 80\%$ predicted
- **GOLD II**: Moderate, $50\% \leq \text{FEV}_1 < 80\%$ predicted
- **GOLD III-IV**: Severe-Very Severe, $30\% \leq \text{FEV}_1 < 50\%$ predicted, $\text{FEV}_1 < 30\%$ predicted

**Mild**
- SABA
  - *when necessary*
  - or Anti-cholinergic

**Moderate**
- LABA
  - or Anti-cholinergic

**Severe**
- LABA
  - or Anti-cholinergic
  - + ICS

**Very Severe**
- LABA
  - and/or Anti-cholinergic
  - + ICS

**Non-Pharmacologic**:
- Smoking cessation
- Physical activity
- Pulmonary rehabilitation and physical activity
- Add long-term oxygen if chronic respiratory failure
- Consider surgical treatments for selected patients (lung volume reduction surgery or lung transplantation)

*Source: Cowen Report, March 2017; American Lung Association; Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines.*
However, the New Classification System of GOLD A-D is Not as Predictive of Outcomes as Initially Thought

COPD assessment tool refined from GOLD 1-4 to ABCD

"As a practicing physician, it is very difficult to pigeon hole patients into one of these categories because there is tremendous variability in terms of their clinical presentation and the impact of their disease on their overall health." – Dr. Robert Vender, MD

Marketed drugs for COPD address the following aspects and include:

- Airflow Obstruction (e.g., glycopyrronium, umeclidinium, formoterol/glycopyrronium, etc.)
- Bronchospasm (e.g., aclidinium)
- Bronchospasm/airflow obstruction + secondary prevention of acute exacerbations (e.g., tiotropium, salmeterol/fluticasone, vilanterol/fluticasone)
- Secondary prevention of severe acute exacerbations only (e.g., roflumilast)

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Disease Modification Remains the “Holy Grail”; New Targeted Therapies Could Have a Significant Impact in COPD

♦ Besides improving airflow obstruction and providing symptom relief, there’s a high unmet need for novel drug therapies to modify the disease. In addition, a great deal of attention needs to be put on management of co-morbidities that have a significant impact on patient outcomes.

   a. Reduce the severity of exacerbations and/or prevent exacerbations
   b. alter disease progression
   c. reduce mortality

Nearly 70 Agents with Novel Mechanisms are in Early Stages of Clinical Development for COPD

AstraZeneca bought Pearl Therapeutics and its LABA/LAMA COPD therapy in 2013 for $1.15B.

In 2014, AstraZeneca agreed to a strategic transaction with Almirall in respiratory disease.

Sunovion acquired Elevation Pharma in a $430M buyout in 2012.
Special Acknowledgements

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Executive Chairman  
Defined Health Inc, a Cello Health business

Akash Katakam  
Analyst  
Defined Health Inc, a Cello Health business
Aruni S. Arachchige Don, Ph.D.
Senior Consultant, Defined Health, a Cello Health business

♦ Aruni’s client work encompasses opportunity assessments, therapeutic area growth strategy and search projects, as well as the identification and evaluation of partnering opportunities. Since joining Defined Health in 2013, she has contributed to projects that span the therapeutic landscape, with special emphasis on projects in respiratory. In addition, Aruni is responsible for leading the market access, reimbursement and pricing work at Defined Health, which includes qualitative one-to-one discussions with payers and value-based pricing modeling.

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- Dr. Rahman is Associate Professor of Environmental Medicine at the Department of Environmental Medicine (Lung Biology and Disease Program), University of Rochester Medical Center.
- He has a dedicated research program to understand the cellular and molecular mechanisms of the pathogenesis of COPD and the potential benefit of therapeutic interventions.
- He has spent over 18 years studying the lung cellular and molecular responses to inhaled toxicants. Dr Rahman's main research interests include understanding the epigenetics (chromatin remodeling), NF-κB regulation, and oxidant/antioxidant imbalance in smokers and patients with asthma and COPD as well as cellular and molecular redox mechanisms of lung inflammation, lung cancer and COPD.
- Dr. Rahman is an author of over 200 publications in internationally renowned peer-reviewed journals, and is invited to write reviews and editorials in journals and chapters in medical text books.
- Dr. Rahman is an Associate Editor and a member of the editorial boards of several international journals including Experimental Lung Research, American Journal of Physiology, Lung Cellular and Molecular Biology, International Journal of COPD, Respiratory Research, Current Drug Targets, Inflammation and Allergy, Current Respiratory Medicine Reviews, Antioxidants Redox Signaling and The Open Respiratory Medicine Journal. He has been serving on various National Institutes of Health, USA study section rosters since 2005. He is a full faculty member of F1000 Medicine team.
Topics for Q&A Session:

♦ Definition of COPD
♦ Updated guidelines for diagnosis and management of COPD, including the new system for classification of patients
♦ Current understanding of COPD biomarkers and disease pathogenesis
♦ Genetics and the interaction between genes and the environment and how that contributes to COPD pathogenesis
♦ Drug development, including past challenges
♦ COPD pipeline, novel mechanisms and potential new drug targets
♦ Final thoughts
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