**Unmet need in the treatment and management of COPD**

Chronic obstructive pulmonary disease (COPD) affects 300 million people worldwide and is now the second leading cause of death in the U.S. The global COPD therapeutic market is estimated to reach $15.6 billion by 2019.

Acute exacerbations of COPD (‘lung attacks’) account for 50-70% of direct costs of COPD management, and there is currently no way to identify high-risk patients. Overlapping symptoms with other conditions such as heart failure and myocardial infarction also make diagnosis and treatment of COPD a major challenge.

**Blood tests to prognose and diagnose acute exacerbations of COPD**

The PROOF Centre is developing prognostic and diagnostic biomarkers for better management of COPD exacerbations. Identifying patients early in clinical presentation will allow for more aggressive therapy and slow disease progression. For pharmaceutical companies, our markers can also be used to identify responders to medicines aimed at reducing lung attacks.

**FIGURE 1.** We have accessed over 200 COPD patients from GSK’s ECLIPSE cohort for biomarker discovery analysis. To date, we have identified molecular biomarker panels that predict the risk of “imminent” lung attacks (IE) – those within 30-60 days of the blood test.

**FIGURE 2.** The biomarkers can prognose exacerbations within 30 or 60 days with an area under the receiver operating characteristics curve (AUC) of 0.72-0.73 – better prediction than that of a common physiological marker for COPD, FEV1% (forced expiratory volume in 1 second).
mRNA expression and protein panels identified that prognose exacerbation

✓ Replication of mRNA expression and protein panels
✓ Migrate biomarkers onto clinical platforms
✓ Clinical validation
✓ Clinical utility

FIGURE 3. Our COPD biomarker program began in 2009, with partners such as GSK ECLILPSE and Genome BC. In our discovery phase, mRNA expression was assessed using Affymetrix microarrays and protein expression by non-targeted or semi-targeted mass spectrometry. In the current phase of the project funded by Genome Canada and partners (2013-2017), we will use systems science strategies to identify additional biomarkers and replicate biomarkers using other well-characterized COPD cohorts (e.g., MACRO, ConCOLD, STATCOPE, CARTaGENE, LEUKO, TNFα). The replicated biomarkers will then be transferred onto clinical platforms and implemented in clinical laboratories for analytical and clinical validity studies.

Socioeconomic Value:

- The impact of COPD and acute exacerbations on health care systems is profound. In 2010 COPD accounted for nearly $4B in direct and indirect costs. This will more than double by 2030.
- Hospitalization for acute exacerbations accounts for up to 70% of all costs for managing COPD.
- Applying our test for prognosis of acute exacerbations across Canada is projected to reduce national health care spending by $23 billion and save 2.5 million COPD patient quality of life years (QALYs) over a 5-year period.
- Early estimates indicate that a biomarker test that enabled early intervention and disease course modification in patients projected to undergo frequent exacerbations could save $3.6B annually in hospitalization costs in Canada alone.

The PROOF Centre of Excellence is a not-for-profit organization that develops blood tests to better manage patients with heart, lung and kidney disease. With a cross-disciplinary team of people and organizations, including commercial partners, we can speed up the development of these tests, applying them sooner to improve lives.

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