

Study results support funded access to IPF drug

By Mark Pavilons

There may be some hope on the horizon for Canadians suffering from mild to moderate forms of idiopathic pulmonary fibrosis (IPF).

Newly published data is giving patients hope that publicly-funded access to the only approved treatment option may soon be a reality. The Phase 3 ASCEND Study: A Randomized, Double-Blind, Placebo-Controlled Trial of Pirfenidone in Patients with Idiopathic Pulmonary Fibrosis (IPF), was presented at the 2014 International Conference of the American Thoracic Society (ATS) in San Diego, California, and concurrently published in *The New England Journal of Medicine*.

The results confirm the proven efficacy and safety of Esbriet (pirfenidone), the first and only treatment approved in Canada for IPF, a rare, progressive and ultimately fatal lung disease.

The study demonstrated that Esbriet significantly reduced the decline in lung function by 47.9 per cent, as measured by a decline in forced vital capacity of 10 per cent or more. Additionally, the study showed that 27.5 per cent of patients on Esbriet experienced a reduced decline of the 6-minute walk distance (6MWD), and almost half (43 per cent) saw an improvement in progression-free survival (PFS) with IPF. Importantly, a pooled analysis of data from ASCEND and two previous phase 3 trials (CAPACITY) with Esbriet showed that the risk of all-cause mortality in IPF patients was reduced by 48 per cent compared with placebo.

As we've seen in the recent articles published in the *New England Journal of Medicine* and presented at ATS, the ASCEND data further reinforces the extensive body of clinical evidence and international expert consensus supporting the use of Esbriet for adults with a diagnosis of mild to moderate IPF, said Dr. Shane Shapera, respirologist at Toronto General Hospital, University Health Network. Also, the results of the INPULSIS study provide evidence that another agent, nintedanib, may add a second drug to our arsenal against this terrible disease. These results are major breakthroughs and I urge the government to review the evidence and re-evaluate their decision on public funding of Esbriet for patients with IPF.

The ASCEND trial data has given the IPF community renewed hope, it's like a breath of fresh air for those who have been desperately awaiting the results of this study, said Robert Davidson, president and founder of the Canadian Pulmonary Fibrosis Foundation (CPFF). The fact that Esbriet has now been confirmed to not only slow disease progression, but also to reduce the risk of death, means that the provinces and territories must heed the evidence from ASCEND and make Esbriet immediately accessible to patients whose lives depend on it.

Davidson and King resident Barbara Barr are leading the charge locally.

Barr was diagnosed in 2012. Her optimism and knowledge about the disease keeps her fired up and ready to put pressure on elected officials and the health care system. She's not letting the disease slow her down, despite being on oxygen 24/7 and carrying around her portable breathing apparatus.

She still has a lot of limitations and that's where Esbriet can help. Barr admits that it's not a cure, but it does treat the symptoms. The seemingly unfair approach to drug accessibility gets her goat at times.

Where do you draw the line and what do you have to do to deserve attention??she asked. Esbriet will give us time, she said.

Despite disease severity, the absence of other treatment options, and a priority review by Health Canada, the Common Drug Review (CDR) recommended that public drug programs not list Esbriet due to a lack of evidence, despite governments of more than 13 European countries providing public funding based on the same data. The resulting lack of government funding for Esbriet has been especially devastating for seniors who are most affected by this disease, as they rely primarily on public drug programs.

Even with all-party support from elected officials in many provinces including Ontario, government decision-makers have refused to grant IPF patients access to a drug prescribed as medically necessary by doctors who are experts in this rare disease.

It has been extremely disheartening to see our government leaders turn their backs on us at our greatest time of need, as we watch members of our community decline and succumb to this horrible disease, said Barr. Our resolve has been greatly bolstered by the publication of this new data in one of the world's leading medical journals, weighty evidence that no government decision-maker can or should ignore.

Idiopathic Pulmonary Fibrosis (IPF) is a rare, progressive and fatal lung disease that has no known cause. It is characterized by scarring of the lungs, which hinders a patient's ability to breathe. Up to 30,000 Canadians are believed to be affected by all forms of PF, with an estimated 3,000 to 5,000 suffering from mild to moderate IPF. Typically diagnosed later in life, IPF has a life expectancy of just two to five years, which is similar to many other malignant diseases, including lung, breast and colon cancer. However, some rapidly progressing cases can be lethal within months of diagnosis.