
ALung to Pursue SFDA Approval of Hemolung RAS in China



ALung Technologies, Inc., a leading developer of innovative respiratory assist devices, announced on May 21, 2013 that it has signed an agreement with Curative Medical, Inc. to pursue China's State Food and Drug Administration ("SFDA") approval for the Hemolung Respiratory Assist System (RAS).

Under the terms of the agreement, Curative Medical will supervise a clinical trial of the Hemolung RAS which provides Respiratory Dialysis® for patients in acute respiratory failure. ALung will contribute all of the necessary equipment and protocol support for the duration of the trial. Commercial distribution of the device in China is expected following receipt of SFDA approval.

"There is a clear clinical need for the Hemolung RAS in China," said Peter DeComo, Chairman and CEO of ALung. "Over 65 million Chinese suffer from chronic obstructive pulmonary disease, primarily due to high rates of tobacco use. When patients with advanced COPD suffer sudden worsening of their symptoms, known as an acute exacerbation, they will sometimes require intubation and invasive mechanical ventilation as a lifesaving measure. With the Hemolung RAS, we can actually help these patients avoid intubation, allowing them to remain awake, communicate, and participate in their own rehabilitation."

ALung's agreement with Curative Medical was facilitated by David Iwinski of Blue Water Growth, a global business consulting firm. "We found a good partner in Curative given their strong position as leading developer and distributor of cardiopulmonary products in China," said Nicholas Kuhn, President and Chief Business Officer of ALung. "Blue Water Growth was instrumental to the formation of this partnership, helping us successfully navigate what was a rather complicated process."

Earlier in 2013, ALung was granted a Health Canada License and the CE Mark, allowing the Hemolung RAS to be marketed in Canada and throughout the European Union.

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