

Clinical Value Proposition

In vitro diagnostic technology that can identify in a blood sample with high reliability (AUC 0.92) if a Resistant Hypertension (RH) patient may decrease blood pressure levels by Continuous Positive Air Pressure (CPAP) treatment

Patients Value Proposition

A companion diagnostic test for RH and OSA patients. **Results in less than 2 hours !**

A personalized treatment at the Point of Need.
Treating two comorbid pathologies in one (RH and OSA)

Increasing lifespan and life quality to RH patients. Reduction of health care costs

Products

- **HIPARCO test** : the 2-hrs blood test performed by Q-PCR reaction
- **HIPARCO score** : the translation of the Q-PCR expression results into a report for clinicians, supporting the decision for CPAP treatment convenience
- **Market introductions**
 - First Introduction within 2 years
 - Full Launch scheduled for 3 years

CIBERES

- CIBERES is the respiratory area of CIBER the world-renowned multidisciplinary research network in Spain
- CIBERES has international collaborations with world-class respiratory researchers from US and European countries.

Scientific and Clinician Team

- Specialists in sleep apneas and cardiovascular comorbidities. Members: Dr. Ferran Barbé (CIBERES' Scientific Director), Manuel Sanchez de la Torre (Sleep Apnea CIBERES' coordinator) and Dr. David Gozal (President of the American Thoracic Society)

Hypertension affects more than 25% of all adults in the world, of which 30-40 million people suffer Resistant Hypertension

Treating Resistant Hypertension efficiently with CPAP

Resistant hypertension (RH) patients cannot get their blood pressure decreased despite using 3 or more drugs, such as spironolactone, ...

Around 80% of RH patients also suffer from Obstructive Sleep Apnea (OSA). OSA can be treated by Continuous Positive Air Pressure (CPAP) as a current practice.

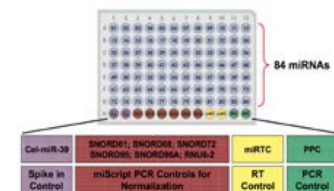
It is demonstrated in clinical studies that CPAP treatment also reduces the blood pressure of RH patients. Treating high blood pressure is crucial in the prevention of cardiovascular events as it is the highest morbidity risk.

Hence, offering CPAP treatment efficiently to the millions of RH patients provides simultaneously 2 benefits: the OSA treatment and the lowering of the blood pressure.

Improving the efficiency of CPAP: the HIPARCO score test

We have demonstrated that for 70% of RH patients, CPAP treatment can reduce blood pressure by 11mmHg.

In addition, a rapid (2h) and accurate (AUC 0.92) test, based on microRNA expression profiles from peripheral blood, has been developed (the **HIPARCO test**) and which can easily be applied in clinical settings where RH patients arrive (e.g., hypertension units in public and private hospitals).



The readout of the test is a score (the **HIPARCO score**) that shows whether a patient is a likely responder or not in terms of blood pressure decrease.

HIPARCO: the companion diagnostic of choice for RH patients.

(*) Scientific data published in JACC *Sanchez de la Torre M J Am Coll Cardiol. 2015 Sep 1;66(9):1023-32* with an editorial from Dr. Valentí Fuster.

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Worldwide Licensing Opportunity

After preclinical validation of technology, CIBERES offers a License to Partners to use all IP and Know-How to commercialize the **HIPARCO Test**

The first target market are the **Hospital Hypertension Units**

A detailed data package on the Technology is available under CDA.

Target Product Profile

Label A marker for predicting the response for CPAP of RH patients

HIPARCO Score
The readout of the test as a score showing whether a patient is a likely responder or not in terms of blood pressure decrease

Accuracy in predicting CPAP response : >95%

Pricing

EU	€ 200 – 600 (est)
USA	€ 200 – 400 (est)
Japan	€ 200 – 800 (est)

Key Economical Considerations

- Region : Europe, USA and Japan
- Time-to-market : 2 years

- Peak annual Sales : **€500M to €750M**
- Tests per Year : **1.5 M HIPARCO tests**

- 10-year cumulative savings for the Health Care for treating RH and CVD : **>€100B !**

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The HIPARCO Test and Score for each RH patient

The diagnostic test consists in the quantification of 4 specific microRNAs (miRNAs) from peripheral blood and the application of a score parameter. Results are translated into a report with the prediction of blood pressure response to CPAP for this particular patient

IP and Know How

The Intellectual Property rights encompass the use of miRNAs, kit, and applications. The fully-owned patent PCT/EP2015/080183 is in national phases since June 2017 and covers the IVD method, the kit and it's use.

Easy adoption

Low adoption hurdles to execute experiments for technicians and easy to use with existing devices used in clinics for miRNA quantification.

	Clinical Value	Economic Value
Patient	<p>Ensured to be using an effective RH treatment</p> <p>Avoid additional complications for the non-responders (to CPAP)</p> <p>Reducing probability to develop other comorbid pathologies</p>	<p>Quality of life</p> <p>Reduced number of medical and hospital visits</p>
Clinician	<p>Best option for identifying effectiveness of RH treatment.</p> <p>Fast results and easier decision</p> <p>Positive control of blood pressure for 70% of RH patients. Avoiding additional complications to CPAP non responder patients.</p> <p>Less complications due to accumulative cardiovascular events.</p>	<p>Reduced risk of cardiovascular events and associated costs</p> <p>Less secondary effects to treat due to non effective treatments</p> <p>Shorter waiting list for specialists</p>
Central Lab	<p>Quick and easy diagnostic test with report</p>	<p>Only to be done once per patient</p>
Health Care ("HC")	<p>Saving Lives</p> <p>Reduction of cardiovascular events and hospitalizations</p> <p>Control of other comorbid associated pathologies.</p>	<p>2800€/patient/year savings</p> <p>Shorter waiting lists in hospitals (UCI and surgical interventions...)</p>

Current Clinical Study– Partners

Clinical validation studies in collaboration with 7 Hospitals Sleep and Hypertension units: Hospital Arnau de Vilanova-Santa Maria (Lleida); Hospital del Mar (Barcelona); Hospital La Fe. (Valencia); Hospital de Araba (Vitoria); Hospital Parc Taulí (Sabadell); Hospital San Pedro de Alcántara (Cáceres); Hospital La Paz (Madrid).