Diagnosis and prognosis in heart failure: Biomarker’s panel for myocardial fibrosis

- **Heart Failure (HF)** is a chronic, progressive condition in which the heart muscle is unable to pump sufficient quantity of blood through the arterial system.
- **Myocardial fibrosis**, characterized by alterations in the quantity and quality of the collagen network, is involved in the development and progression of HF.
- There is an unmet need to identify inadequately-treated, high risk HF patients with alterations in collagen type I quantity (CD) and cross-linking (CCL) leading to the development of fibrosis.
- A **panel of biomarkers**, measurable in blood, has been identified and validated for identifying alterations in CD and CCL, useful for risk stratification, personalized therapy and monitoring of therapy effectiveness in patients with HF.
- **Primary Indication**: Heart Failure.

**Scope of the problem**
- In the US, over 5.7 million people are currently living with HF. An estimated 400,000 to 700,000 new cases of HF are diagnosed each year.
- About half of people who develop HF die within 5 years of diagnosis. HF is the cause for 12-15 million medical visits per year and 6.5-7 million days of hospitalization per year.
- Myocardial fibrosis is an independent predictor of mortality and morbidity in HF patients.

**Patient need addressed**
Noninvasive techniques that can quickly identify the alterations in the collagen network.

**Panel of Biomarkers**
- PICP: Index of CD.
- The ratio between CITP (cross-linked peptide) and MMP-1 (protease): Index of the degree of CCL.
- miR-19b: Index of the degree of CCL.

**Clinical Indications**
HF patients

**Competitive Advantage**
Allows the identification of alterations of the myocardial collagen network beyond what is given by conventional imaging technology. The panel is cheaper and less time- and personnel-consuming than available non-invasive imaging methodologies. The identification of the predominant alteration may influence therapy election.

**Proof of Concept**
Research in human patients. The proposed biomarkers reflect the myocardial alteration under study. They have a prognostic value for predicting hospitalization for HF or death.

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