**For immediate release**

<XXXX>, 2021

**FDA Approves Treatment for Patients Suffering from Long-Standing Persistent Atrial Fibrillation**

*This is the only FDA approval of its kind—minimally invasive ablation therapy—for more than 3.5 million patients in the United States with long-standing persistent atrial fibrillation (AF).*

*It significantly expands AF treatment options for this category of AF patients.*

*With this therapy, the superiority trial showed a 35% difference in effectiveness at 18 months compared to endocardial RF ablation alone.*

The U.S. Food and Drug Administration (FDA) has approved the EPi-Sense® System to treat patients diagnosed with long-standing persistent atrial fibrillation (AF). We at <HOSPITAL NAME> are pleased to announce that we offer this therapy to treat long-standing persistent AF patients, who until now had very few treatment options.

The minimally invasive Hybrid AF™ Convergent procedure involves epicardial (outside of the heart) ablation plus endocardial (inside of the heart) radiofrequency (RF) ablation—thereby treating 2 key trigger areas where AF can begin. The CONVERGE IDE clinical trial demonstrated superiority in the Hybrid AF Convergent arm compared to endocardial RF catheter ablation, showing a 35% difference at 18 months in long-standing persistent AF patients. There was also a 37% improvement in AF burden (at 18 months) in favor of the Hybrid AF Convergent procedure.

One in 4 adults over age 40 will develop atrial fibrillation in their lifetime.1 AF affects about 33 million people worldwide,2 and about 8 million people in the U.S.3 It also increases a person's risk of stroke and heart failure, and it is linked with increased risk of mortality.

Approximately 45% of AF patients have long-standing persistent AF, affecting more than 3.5 million patients in the United States.3 “Given that these patients have no other comparable treatment options today, our electrophysiology practice will now offer the Hybrid AF Convergent procedure,” said <HOSPITAL MD, TITLE>.

The Hybrid AF Convergent procedure is the only proven minimally invasive ablation therapy to treat patients who have been in AF for more than one year.

**18-Month Data Reveal Durability**

Both 12-month (Table 1) and 18-month (Table 2) data from the CONVERGE IDE trial show that the Hybrid AF Convergent procedure provides durable, long-lasting efficacy. In the Hybrid AF Convergent arm, 61% of patients were free from all arrhythmias at 18 months, versus 26% of the patients treated with endocardial RF catheter ablation alone. Moreover, 68% of patients in the Hybrid AF Convergent arm were free from AF, versus 30% in the catheter ablation arm.

“These 18-month results are incredible and demonstrate the durability of the procedure,” said principal investigator David DeLurgio, MD. “This is a key finding from the trial and shows that patients who undergo a Hybrid AF Convergent procedure should expect continued freedom from atrial fibrillation.”

| **Parameter** | **Hybrid AF Convergent Ablation Arm****(N=38)** | **Endocardial RF Catheter Ablation Arm****(N=27)** | **Difference****(Convergent – Control)** |
| --- | --- | --- | --- |
| Freedom from AF/AFL/AT from 3-month blanking period through 12 months\* *n%, (95% Confidence Interval)* | 65.8%(50.7%, 80.9%) | 37.0%(18.8%, 55.3%) | 28.8% in favor of Convergent |
| >90% burden reduction at 12 months\**n%, (95% Confidence Interval)* | 78.9% (66.0%, 91.9%) | 46.2% (27.0%, 65.3%) | 32.7%in favor of Convergent |
| Freedom from AF through 12 months \**n%, (95% Confidence Interval)* | 71.1% (56.6%, 85.5%) | 37.0% (18.8%, 55.3%) | 34.1%in favor of Convergent |

| **Parameter** | **Hybrid AF Convergent Ablation Arm****(N=38)** | **Endocardial RF Catheter Ablation Arm****(N=27)** | **Difference****(Convergent – Control)** |
| --- | --- | --- | --- |
| Freedom from AF/AFL/AT from 3-month blanking period through 18 months\* *n%, (95% Confidence Interval)* | 60.5%(45.0%, 76.1%) | 25.9% (9.4%, 42.5%) | 34.6% in favor of Convergent |
| >90% burden reduction at 18 months\**n%, (95% Confidence Interval)* | 73.0% (58.7%, 87.3%) | 36.0% (17.2%, 54.8%) | 37.0%in favor of Convergent |
| Freedom from AF through 18 months \**n%, (95% Confidence Interval)* | 68.4% (53.6%, 83.2%) | 29.6% (12.4%, 46.9%) | 38.8%in favor of Convergent |

**About the CONVERGE IDE Trial**

The CONVERGE IDE trial is a prospective, superiority, randomized, controlled pivotal trial to evaluate the success of Hybrid AF Convergent ablation compared to endocardial RF catheter ablation for patients with persistent or long-standing persistent AF. The procedure combines a minimally invasive, closed chest epicardial ablation performed by a surgeon with endocardial RF catheter ablation performed by an electrophysiologist. The trial enrolled 153 patients at 27 locations (25 in the United States and 2 in the United Kingdom). Patients were randomized at a rate of 2:1 and received either Hybrid AF Therapy Convergent or an endocardial RF catheter ablation alone. David DeLurgio, MD, of Emory St. Joseph’s Hospital in Atlanta, Georgia, was the trial’s national principal investigator.

\*Data based on the post-hoc analysis of long-standing persistent AF sub-groups (N=65)

**EPi-Sense® Guided Coagulation System**

**Indications**: The EPi-Sense® Guided Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery for the treatment of arrhythmias including Atrial Fibrillation (AFIB) or Atrial Flutter (AFL).

**Contraindications:** Patients with presence of left atrial thrombus, a systemic infection, active endocarditis, or another infection local to the surgical site at the time of surgery. Patients with Barrett’s Esophagus.

1. Lloyd-Jones, D.M., et al. (2004). Lifetime risk for development of atrial fibrillation. Circulation, 110, 1042-1046. doi: 10.1161/01.CIR.0000140263.20897.42.

2. Rahman, F., et al. (2014). Global epidemiology of atrial fibrillation. *Nature reviews cardiology,* 11, 639-654. https://doi.org/10.1038/nrcardio.2014.118

3. Colilla, S. et al. (2013). Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. *American journal of cardiology,* 112(8), 1142-1147.