

**EHMTC-0306  
POSTER SESSION C**

**PATHWAY REGISTRY 12 MONTH INTERIM  
RESULTS – LONG-TERM THERAPEUTIC  
EFFECTIVENESS OF SPHENOPALATINE  
GANGLION (SPG) STIMULATION FOR  
CLUSTER HEADACHE (CH)**

M. Barloese<sup>1</sup>, H. Kaube<sup>2</sup>, U. Reuter<sup>3</sup>, P. Stude<sup>4</sup>,  
A. Böger<sup>5</sup>, T. Jürgens<sup>6</sup>, C. Gaul<sup>7</sup>, K. Solbach<sup>8</sup>, P. Storch<sup>9</sup>,  
C. Wöber<sup>10</sup>, A. Straube<sup>11</sup>, O. Summ<sup>12</sup>, A. Goodman<sup>13</sup>,  
A. Caparso<sup>13</sup>, R. Jensen<sup>1</sup>, A. May<sup>14</sup>

<sup>1</sup>Rigshospitalet-Glostrup- University of Copenhagen, Danish  
Headache Centre- Department of Neurology, Glostrup,  
Denmark

<sup>2</sup>Neurologie und Kopfschmerzzentrum Muenchner Freiheit,  
Neurologie und Kopfschmerzzentrum Muenchner Freiheit,  
Munich, Germany

<sup>3</sup>Charite – Mitte Campus, Neurologische Klinik und  
Poliklinik, Berlin, Germany

<sup>4</sup>Schmerztherapie- Geriatrie und Palliativmedizin,  
Schmerztherapie- Geriatrie und Palliativmedizin, Bochum,  
Germany

<sup>5</sup>Rotes Kreuz Krakenhaus Kassel, Rotes Kreuz Krakenhaus  
Kassel, Kassel, Germany

<sup>6</sup>University Medical Center Rostock, Department of  
Neurology, Rostock, Germany

<sup>7</sup>Migraine- and Headache Clinic Königstein, Migraine- and  
Headache Clinic Königstein, Königstein, Germany

<sup>8</sup>Universitätsklinikum Essen, Klinik und Poliklinik für  
Neurologie, Essen, Germany

<sup>9</sup>Universitätsklinikum Jena, Klinik f.Neurologie, Jena,  
Germany

<sup>10</sup>Medizinische Universität Wien, Klinik für Neurologie,  
Vienna, Austria

<sup>11</sup>Klinikum der Universität München, Neurologische Klinik  
und Poliklinik, Munich, Germany

<sup>12</sup>Universitätsklinikum Münster, Klinik für Neurologie,  
Münster, Germany

<sup>13</sup>Autonomic Technologies- Inc., Clinical, Redwood City, USA

<sup>14</sup>Universitäts-Klinikum Hamburg-Eppendorf, Department of Systems Neuroscience, Hamburg, Germany

**Background:** The Pathway Registry evaluated sphenopalatine ganglion (SPG) stimulation for cluster headache (CH). Previously, in a randomized, double-blind, multicenter study (Pathway CH-1), 68% of patients experienced clinically significant improvements. We evaluated long-term therapeutic effectiveness of SPG stimulation.

**Method:** Acute pain response following SPG stimulation and attack frequency reduction were analyzed at 12 months following SPG microstimulator insertion. Acute effectiveness is relief/freedom from  $\geq$  moderate pain, or freedom from mild pain. Therapeutic responders achieved acute effectiveness in  $\geq 50\%$  of attacks by end of stimulation, or  $\geq 50\%$  attack frequency reduction versus baseline. Patients were similarly evaluated for  $\geq 75$  and  $\geq 30\%$  therapeutic response.

**Results:** Through March 2016, 119 patients were enrolled. 80 patients (74 chronic CH, 6 episodic CH) had a microstimulator inserted and progressed through the 12 month study visit ( $374 \pm 31$  days post-insertion, range 322–475).

In these 80 patients (59 male, 21 female, age  $46 \pm 12$  years), baseline attack frequency was  $24.9 \pm 20.8$  attacks/week with severely CH impact (HIT-6:  $64.0 \pm 6.9$ ). 66% (53/80) were therapeutic responders with a response of  $\geq 50\%$ . Frequency responders (43/80) reduced attack frequency by 86% ( $26.5 \pm 23.2$  to  $3.6 \pm 6.6$  attacks/week,  $p < 0.001$ ). Acute responders (25/80) achieved effective therapy in 87% of attacks (4212/4863) by end of stimulation.

46% (37/80) of patients experienced a very strong therapeutic response of at least 75%; 75% (61/80) experienced at therapeutic response of at least 30%.

**Conclusion:** Therapeutic effectiveness of SPG stimulation in chronic medically refractory cluster patients (Pathway CH-1 trial) is confirmed in an open label registry of a large series of cluster patients through 12 months.

Conflict of interest

Disclosure statement:

AG and AC are employees of Autonomic Technologies, Inc.