Press Release of DOASENSE GmbH

Presentation of First-Ever Point-of-Care Urine Test for Direct Oral Anticoagulants (DOACs)

HEIDELBERG – 01 August 2017 – DOASENSE GmbH with its headquarters in Heidelberg/Germany has presented for the first time a point-of-care urine test for direct oral anticoagulants (DOACs) to a professional audience at the international ISTH Congress in Berlin. As the use of DOACs is getting more and more common, the need for specific anticoagulant checks is likewise increasing. These checks, however, are very time-consuming and often unavailable. DOASENSE has now developed a fast test that produces reliable results for Factor Xa and Thrombin inhibitors within 10 minutes on the basis of a urine test using a simple test strip, as it was announced at the ISTH Congress in July.

Direct oral anticoagulants (DOACs) were introduced as early as 2008 but their use was by and large limited to surgical indications as alternatives to heparins. DOACs were used extensively only after indications expanded to stroke prophylaxis for patients with atrial fibrillation and as a therapy for deep-vein thrombosis and pulmonary embolism. Medical associations also recommend the use of DOACs rather than Vitamin K antagonists in these indications.[1]

In the last five years the share of DOACs among all oral anticoagulants prescribed increased from 15% in 2012 to 67% in March 2017. In Germany the sales increase of only the oral direct Factor Xa inhibitors amounted to roughly 30% from April 2016 to March 2017.[2]

DOACs do not need any regular laboratory checks as is absolutely imperative in the case of Vitamin K antagonists. All the same, there are some medical situations in which the presence or absence of a DOAC is crucial for therapeutic decision making. This concerns e.g. patients

- suffering from acute stroke
- in need of urgent or emergency operations
- in need of thrombolytical therapy
- with yet unexplained bleeding
- with bleeding under a DOAC when an antidote is needed
- with recurrent thromboembolism under DOAC
- who are unconscious if bleeding under a DOAC must be precluded
- before spinal anaesthesia.

As customary coagulation tests like prothrombin time (PT), aPTT, thrombin time (TT), activated clotting time (ACT) and others have only limited validity, intricate tests by means of chromogenic substrate or mass spectrometry are required, but they are both time-consuming and labour-intensive and can be carried out only by highly specialized laboratories. This will delay the necessary swift therapeutic decision.[3, 4, 5]

For these reasons the DOASENSE GmbH, founded in Heidelberg by Professors Job Harenberg and Roland Krämer, have developed a patented high-speed urine test for DOACs with test

strips. This qualitative test answers the question whether a patient has ingested a DOAC or not within 10 minutes with a sensitivity and specificity of > 98%. Both Factor Xa and Thrombin inhibitors can be determined jointly with the help of a single test strip.[6] Thus, the necessary therapeutic decision can be taken as quickly as possible.

This DOAC point-of-care test (POCT) was presented to a wide professional audience for the first time in July at the Congress of the International Society on Thrombosis and Haemostasis (ISTH). The presentation was met with great interest by participants; the DOASENSE symposium at the ISTH was packed to capacity with an audience of more than 350 participants. Founder and Managing Director Job Harenberg commented: "We are deeply impressed by the enthusiastic reception with which all the experts here in Berlin welcomed our new test method."

DOASENSE plans to market the POCT product in Germany in late 2017.

References:

[1] Kirchhof, P. et al; Eur Heart J 2016; 37: 2893-962

[2] Quintiles IMS Marktbericht. 1. Quartal 2017

[3]Dubois V et al; Thromb J 2017; 15:14. doi: 10.1186/s12959-017-0137-1.

[4] Harenberg J et al., Clin Chem Lab Med. 2016; 54:275-83

[5] Schreiner R et al; Res Pract Thromb Haemost. 2017; 1 (Suppl. 1): PB 491

[6] Harenberg J et al; Res Pract Thromb Haemost. 2017; 1 (Suppl. 1): PB 454

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