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PROGNOSIS Study Published in *The New England Journal of Medicine* Reveals Innovative Roche Blood Test Can Be Used as a Predictive Tool for Preeclampsia

Study results validate the clinical value of measuring sFlt-1/PlGF ratios in women with suspected preeclampsia,¹ accounting for more than 4 out of every 10 maternal deaths each year globally.²

- The PROGNOSIS study is the first multi-center, large-sample study to demonstrate the prognostic value of the Roche Elecsys® preeclampsia test to predict the absence of preeclampsia for one week, and the development of preeclampsia within the subsequent four weeks in women with clinical suspicion of the syndrome.
- The addition of the sFlt-1/PlGF ratio measurement to proteinuria and blood pressure measures gives better prediction of preeclampsia, and can reduce hospitalization pre-diagnosis by 50%.³
- The PROGNOSIS study has highlighted the clinical value of measuring sFlt-1/PlGF ratios in women with suspected preeclampsia.

Roche today announced that the *New England Journal of Medicine* has published the results of PROGNOSIS, a groundbreaking clinical study demonstrating the prognostic value of the company’s Elecsys® sFlt-1/PlGF immunoassay ratio test in predicting which pregnant women are at highest risk of developing preeclampsia,¹ one of the leading causes of death and complications for mothers and their unborn babies.²

“The emotional benefits of the test are very important: preeclampsia can develop quickly and symptoms can develop even in women who so far have had a healthy pregnancy,” said Professor Harald Zeisler of the Department of Obstetrics and Gynecology at Medical University Vienna, Austria, and an investigator in the PROGNOSIS study. “If we can tell a patient with signs or symptoms that she has a low sFlt-1/PlGF value, and therefore a low risk of developing preeclampsia within short term, that’s a big advantage. On the other hand, women with high sFlt-1/PlGF values can be referred to hospitals with neonatal and adult intensive care units, where they can receive the specialist care they need.”

As well as potentially saving lives, the more accurate diagnosis of preeclampsia may also have positive
economic impacts on healthcare systems. In 2005, the average cost of preeclampsia, excluding normal delivery costs, was an estimated GBP 9,009 per pregnancy. With an estimated 8.5 million women affected by preeclampsia every year, the annual cost of preeclampsia worldwide is estimated to be GBP 76.6 billion (based on the 2005 estimate), representing a major financial burden. Clinical use of the sFlt-1/PlGF ratio to predict and diagnose preeclampsia could help reduce the associated health care costs, by cutting both inappropriate discharges and unnecessary hospitalizations. Routine use of the Roche preeclampsia test could reduce by 50% the number of women hospitalized prior to preeclampsia diagnosis, leading to a cost savings of approximately 400GBP per patient.

“The PROGNOSIS study is the first to demonstrate that the Elecsys® sFlt-1/PlGF immunoassay ratio can reliably rule out preeclampsia for one week,” said Roland Diggelmann, Chief Operating Officer, Roche Diagnostics. “We’re delighted to see the results published in such a world-renowned journal as the New England Journal of Medicine, and confident the findings will have a positive impact on the prediction and clinical management of this serious medical condition. They also support our vision to bring medical value to patients, which will enable proactive disease management and better patient care.”

About PROGNOSIS
The PROGNOSIS study has demonstrated that low ratios of the proteins sFlt-1 and PlGF in the blood of women showing the signs and symptoms of preeclampsia can predict the absence of the condition within a period of one week (the rule-out claim). The data published today show that an sFlt-1/PlGF ratio of 38 and below can rule out the development of preeclampsia within the next week with a very high confidence level of 99.3%. Identifying women who are unlikely to develop preeclampsia in the short term will save them from the stress of monitoring and the disruption to their home life caused by a stay in hospital.

PROGNOSIS also demonstrated that an sFlt-1/PlGF ratio greater than 38 may help predict whether women with suspected preeclampsia will develop the condition within four weeks (the rule-in claim), allowing doctors to identify at-risk patients who need close monitoring.

These important new findings represent a step-change in the prediction of preeclampsia in the clinical setting, where the gold standard has traditionally relied on the measurement of proteinuria (protein in the urine) and blood pressure. Unfortunately, both are sub-optimal predictors of which women will develop preeclampsia and how the disease will progress. As a consequence, many women with signs and symptoms of the disease are unnecessarily admitted to hospital for intensive observation and monitoring, resulting in
worry for them and their families, and additional costs to the health provider.

**About preeclampsia**

Preeclampsia develops after gestational week 20, affecting about one in 20 pregnancies, accounting for more than 4 out of every 10 maternal deaths each year around the world.² It is a leading cause of preterm birth and consequent ill-health or death of newborns.² If preeclampsia remains unattended, the mother can go into convulsions, and can even die.⁶ The cause of the disease is not fully understood, but when it develops, the flow of blood through the placenta is reduced which means the baby does not get enough oxygen or nourishment to grow properly.⁷,⁸ Preeclampsia is a disease that does not necessarily have early signs and gets worse over time. It cannot be treated; it can only be resolved by delivering the baby.

**About the preeclampsia test**

The preeclampsia test, called Elecsys® sFlt-1/PIGF immunoassay ratio, assesses the ratio of two proteins sFlt-1 (soluble fms-like tyrosine kinase-1) and PIGF (placental growth factor) found in the mother’s blood. An sFlt-1/PIGF ratio of 38 and below can rule out the development of preeclampsia within the next week with a negative predictive value of 99.3%, whilst a ratio above this cut-off value predicts the development of preeclampsia within four weeks with a positive predictive value of 36.7%.¹ The ratio had previously already been used as an aid in the diagnosis of preeclampsia and it is associated with adverse outcomes for mother and baby.⁹,¹⁰,¹¹ The test is available in all countries accepting the CE mark in Europe, Latin America, Middle East, Africa and Asia. The test is currently not available in the United States and Japan.

**About the PROGNOSIS study**

PROGNOSIS was a multi-center, prospective, double-blind, non-interventional trial evaluating the short-term prediction of preeclampsia, eclampsia and HELLP (hemolysis, elevated liver enzymes, low platelet count) syndrome in pregnant women with suspected preeclampsia. Sponsored by Roche, the PROGNOSIS study aimed to address the limitations of the traditional clinical parameters used to predict preeclampsia, and to demonstrate the utility of the Elecsys® preeclampsia ratio test in this context.¹ Between December 2010 and January 2014, more than 1,270 pregnant women were enrolled at 30 sites in 14 countries. Results of the PROGNOSIS study were published in the *New England Journal of Medicine* in 7 January, 2016.¹ They demonstrated that a ratio of the proteins sFlt-1/PIGF of 38 and below predicts an absence of preeclampsia, eclampsia and HELLP syndrome for one week, whilst an sFlt-1/PIGF ratio above 38 predicts onset of preeclampsia, eclampsia and HELLP syndrome within four weeks.
About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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