**Title: LINC 22: IN.PACT Global Study 5-Y Diabetic & Gender Subgroup Outcomes**

**Participants: Prof Marianne Brodmann**

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**Prof Marianne Brodmann**

- Thank you very much for asking me the questions about the sub-analyses of this long term outcome data of the IN.PACT Global Study with regard to gender aspect of treatment and the diabetic aspect of treatment.

**Study Background**

I think this is a very important study. First of all, females usually have adverse outcome than males especially in the long term. They are not that much included in randomised control studies. It's usually only one third of patients in a randomised control study or in a registry, which are females. So this is a huge data set about females, and females have a worse outcome because they have smaller vessel diameters. They have more complex lesions. They have usually longer lesions. They are much older when they show up. They have more comorbidities. So this counts for adverse outcome. And with what we see in this subgroup analyses is that even if this worse conditions at the beginning when they go into the study and when they are treated with the IN.PACT DCB, they have the same outcome as males in the long term. And I think this is the most important conclusion we can draw out of that, that we can also now treat females in an efficient way with the same outcome as males although they have more comorbidities. They show up at the worst condition already, when they are showing up for a treatment.

**IN.PACT AV Access Drug Coated Balloon**

I think this is, it's a good DCB. It's the one with the most robust data there. It's one with really good long-term outcome data. So, we treat it with a very well adopted technology with a very high performance. So, I think this is the conclusion.

**Key Results**

So the issue with regard to looking at patients with diabetes, you usually have a very high mortality rate, amputation rate because diabetes counts for the development of critical emphysema and therefore for worse outcomes. So we saw the same thing. We saw really good patency data. So this is the efficacy, low TLR data compared to non-diabetics or in the same percentage. So there's no difference between for the efficacy between non-diabetics and diabetics. And yes, patients with diabetes might die a little bit more often than non-diabetics, but this is due to the general conditions they have to the comorbidities. And when we look from this IN.PACT Global Studies sub-analyses, when we look at the mortality rate and compare this with the mortality rate of diabetics with PAD in epidemiological studies it's in the lower range. So, no mortality issue for patients with diabetes if we treat and use the IN.PACT. We have a higher efficacy and modalities in the range of diabetes in general.

**Take-home Messages**

I think we have the first DCB with long-term data, five years, showing excellent results with regard to efficacy and safety in the most complicated patient subgroups.