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# Addendum to Commission A09-02 (Prasugrel for acute coronary syndrome)[1]

## Addendum

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[1]Translation of addendum A11-21 “Addendum zum Auftrag A09-02 (Prasugrel bei akutem Koronarsyndrom)” (Version 1.0; Status: 07.11.2011). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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| Abbreviation | Meaning |
|---|---|
| ACS | acute coronary syndrome |
| ASA | acetyl salicylic acid |
| G-BA | Gemeinsamer Bundesausschuss (Federal Joint Committee) |
| IQWiG | Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care) |
| NSTEMI | non-ST-elevation myocardial infarction |
| STEMI | ST-elevation myocardial infarction |

## 1 Background

In its letter of 15.09.2011, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to provide further information about the Final Report A09-02 (Prasugrel for acute coronary syndrome (ACS)) [1]. Information was requested about the H7T-MC-TACM study mentioned on Page 130 of the Final Report, particularly a specific description of the study design and an answer to the question whether the H7T-MC-TACM study has effects on the assessment, already undertaken by IQWiG, of clopidogrel plus acetylsalicylic acid (ASA) in ACS (A04-01B) [2].

## 2 Response to the research question

IQWiG referred to the H7T-MC-TACM study in the context of preparing the report plan for Project A09-02 [3]. The study was also mentioned in the Final Report of the project. In each case, this mention was made during the evaluation of comments on the report plan and/or preliminary report. The study was not included in the benefit assessment.

The data sources available to the Institute are:

- An entry in the overviews of studies with prasugrel submitted by Lilly Deutschland GmbH as part of the work involved in Project A09-02.
- An entry in the trials registry ClinicalTrials.gov [4].

No study report is available.

The essential characteristics of the study and inclusion/exclusion criteria are shown in Table 1 and Table 2.

The H7T-MC-TACM study enrolled patients with ACS (excluding ST-elevation myocardial infarction (STEMI)) as well as patients with stable angina pectoris. Accordingly, not all the patients who were investigated had also been included in Report A04-01B [2] (patients with non-ST elevation myocardial infarction (NSTEMI) or unstable angina). Moreover, the three-arm study was terminated prematurely after the enrolment of only 29 patients and the observation period was only 11 days. Therefore only the data from a very few patients, observed for a very short time, are available for the assessment of clopidogrel. Furthermore, clopidogrel was administered in a non-approval-compliant dose (saturation dose). In summary, an influence of the results of the H7T-MC-TACM study on the conclusions of Final Report A04-01B [2] can therefore be excluded.

Table 1: Study characteristics

| Study | Study design/ Interventions | Duration of study | Number of randomized patients (ITT population) | Location and period of study | Primary outcome measure |
|---|---|---|---|---|---|
| H7T-MC-TACM | RCT, open-label, parallel<br>Prasugrel (60 mg SSD) + ASA[a]<br>Prasugrel (30 mg SSD) + ASA[a]<br>Clopidogrel (600 mg SSD) + ASA[a] | 11 days (SSD on Day 0, then wash-out) | The study was discontinued after 29 patients had been enrolled.<br>*Planned: 240 patients.* | Germany<br>October 2009 to December 2010 | Measurement of return to baseline platelet function using Accumetrics-VerifyNow™-P2Y12 reaction units and portrayal on the basis of Kaplan-Meier curves after an SSD of 30 mg or 60 mg prasugrel (Day: 3, 5, 7, 9 and 11). |

Italics: information from the manufacturer.
a: ASA could, where appropriate, be administered during the entire study (including wash-out).
ASA: acetylsalicylic acid; RCT: randomized controlled trial; SSD: saturation single dose.

Table 2: Relevant inclusion/exclusion criteria

| Study | Inclusion criteria | Exclusion criteria |
|---|---|---|
| H7T-MC-TACM | Men and women; ≥ 18 to < 80 years;<br>Symptoms of ACS, clinical symptoms of angina or a positive stress test or routine angiography post-stent placement ; co-administration of ASA and a thienopyridine (clopidogrel, ticlopidine or prasugrel) not contraindicated) | STEMI, history of refractory ventricular arrhythmias, implanted defibrillator or congestive heart failure (NYHA ≥ III) within 6 months prior to screening; significant hypertension, patients with history or clinical suspicion of cerebral vascular malformations, TIA or stroke, bleeding disorders. |

ACS: acute coronary syndrome; ASA: acetylsalicylic acid; NYHA: New York Heart Association; STEMI: ST-elevation infarction; TIA: transitory ischaemic attacks.

## 3 References

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4. Eli Lilly. Study to learn when platelets return to normal after one loading dose of anti-platelet drugs in patients with symptoms of acute coronary syndromes (H7T-MC-TACM) [online]. In: ClinicalTrials.gov. 08.02.2011 [accessed: 12.09.2011]. URL: http://www.clinicaltrials.gov/ct2/show/NCT01107899.