

Appendix 1 Table O. On-Label Comparative Study Quality of Life and Satisfaction Outcomes

Investigator (yr, country, ref #)	Study design	Comparisons No. pts (BMP dose)	Patient diagnosis	Surgical intervention	Outcome measure mean score	Outcome measure % improved or success (p-value)	Comment
Boden et al., 2000 USA (71) Lumbar Spine	Multicenter, nonblinded RCT	rhBMP2 (4.2-8.4 mg/pt) n=11	single-level lumbar DDD	single-level primary anterior lumbar fusion with interbody fusion cages plus rhBMP2 or ICBG	SF-36 general health perception subscale Mean score improvement 0, 3, 6, 12, 24 mos rhBMP2 68, 74, 68, 70, 73	All improved over 24 mos. (p not reported)	At 24 mos. 11 of 11 pts in rhBMP2 group rated outcome as excellent; 1 of controls rated outcome as excellent, 1 each good and fair. Mean neurologic scores were increased over baseline at all time points in both groups.
		ICBG n=3			ICBG 59, 57, 75, 64, 67		
Burkus et al., 2002 USA (72) Lumbar Spine	Multicenter, nonblinded RCT	rhBMP2 (4.2-8.4 mg/pt) n=143	single-level lumbar DDD	single-level primary anterior lumbar fusion with interbody fusion cages plus rhBMP2 or ICBG	NR	Patient satisfaction 24 mos rhBMP2 81% satisfied	82% of rhBMP group indicated they would undergo same procedure, compared with 77% of ICBG group
		ICBG n=136			ICBG 80% satisfied		
Burkus et al., 2003 USA (182) Lumbar Spine Note: may include pts in Burkus et al., 2003, (80)	Retrospective combined comparative analysis	rhBMP2 n=277 (dose NR)	single-level lumbar DDD	single-level primary anterior lumbar fusion with interbody fusion cages	NR	NR	
	ICBG n=402						
Dawson et al., 2009 USA (73) Lumbar Spine	Multicenter nonblinded RCT	rhBMP2/CRM n=25 (12 mg/pt)	single-level lumbar DDD	single-level primary instrumented posterolateral	NR	NR	

		ICBG n=21		lumbar fusion plus rhBMP2 or ICBG			
Govender et al. for the BESTT study group 2002 South Africa (74) Open Tibial Fractures	Multi-center, single blind, RCT	rhBMP2 (1) n=151 (6 mg/patient)	Open tibial fracture where the major component was diaphyseal	IM nail fixation and soft tissue management	NR	NR	
	rhBMP2 (2) n=149 (12 mg/patient)						
	(3) n=150 Standard care (IM nail fixation and soft tissue management)						
Swiontkowski et al., 2006 USA (81) Open Tibial Fractures Note: This paper reports on 131 of the same patients included in Govender et al., 2002 (74)	Subgroup analysis of combined data from two prospective randomized trials with identical designs	rhBMP2 (1) n=169 (12 mg/patient)	Acute open tibial fracture	IM nail fixation and soft tissue management	NR	NR	
	(2) n=169 Standard care (IM nail fixation and soft tissue management)						
Boyne et al., 2005 USA (75) Maxillofacial and Dental	Multicenter randomized dose- comparison, safety and efficacy study	rhBMP2/ACS (6-24 mg/pt) n=18	< 6 mm alveolar bone height in the posterior maxilla	staged bilateral or unilateral maxillary sinus floor augmentation	NR	NR	
	rhBMP2/ACS (15-48 mg/pt) n=17						
	AGB n=13						

Fiorellini et al., 2005 USA (76) Maxillofacial and Dental	Double-blind, multicenter randomized, placebo-control dose-comparison, safety and efficacy study	rhBMP2/ACS (mn dose 0.9 mg/pt) n=22	≥ 50% buccal bone loss of the extraction socket(s)	extraction socket augmentation	NR	NR	
		rhBMP2/ACS (mn dose 1.9 mg/pt) n=21					
		Placebo n=17					
		No Tx n=20					
Triplett et al., 2009 USA (77) Maxillofacial and Dental	Multicenter, nonblinded RCT	rhBMP2/ACS n=80 (12-24 mg/pt)	< 6 mm alveolar bone height in the posterior maxilla	staged bilateral or unilateral maxillary sinus floor augmentation	NR	NR	
		AGB n=80					
van den Bergh et al., 2000 Netherlands (82) Maxillofacial and Dental	Retrospective cohort study	rhBMP7/ACS n=3 (2.5 mg/pt)	partly edentulous	maxillary sinus floor augmentation	NR	NR	
		ICBG n=3					
Calori et al., 2008 Italy (78) Long Bone Nonunion	Single-center, nonblinded RCT	rhBMP7/ACS n=60 (3.5-7.0 mg/pt)	post-traumatic atrophic nonunion for ≥ 9 mos, with no signs of healing over the last 3 mos	open reduction internal fixation (ORIF), external fixation (EF), or reamed intramedullary nailing (IM) with rhBMP7 or PRP	NR	NR	
		PRP n=60					

Dahabreh et al., 2008 (83) Long Bone Nonunion	Retrospective cohort study	rhBMP7/ACS n=15 (3.5 mg/pt)	tibial fracture nonunion with clinical and radiographic failure to progress to union for ≥ 9 mos. following initial fracture stabilization	open reduction internal fixation (ORIF), exchange intramedullary nailing (IM), or Ilizarov, with rhBMP7 or ICBG	NR	NR	
		ICBG n=12					
Friedlaender et al., 2001 (79) Long Bone Nonunion	Multicenter, partially blinded RCT	rhBMP7/ACS n=61 (3.5-7.0 mg/pt)	tibial nonunion for ≥ 9 mos, with no signs of healing over the last 3 mos	IM rod fixation with rhBMP7/ACS or AGB	NR	Physician satisfaction 9 mos rhBMP7 86	
		AGB n=61				AGB 90	